EXHIBIT 2

COMMONWEALTH OF MASSACHUSETTS

* * *

MIDDLESEX, SS. SUPERIOR COURT

IN RE:	)	
	)	CA NO: MICV2011-3750M
SPECIALLY ASSIGNED	)	
	)	Master Docket
MESH IMPLANT CASES	)	
	)	

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VIDEOTAPED DEPOSITION OF STEVEN R. LITTLE, Ph.D.

February 13, 2017

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VIDEOTAPED DEPOSITION OF STEVEN R. LITTLE, Ph.D., a witness herein, taken pursuant to MASS. R. CIV. P. 30, by and before Dutcheen O. Cameron, Registered Merit Reporter and Certified Realtime Reporter and Notary Public in and for the Commonwealth of Pennsylvania, at the Pittsburgh Marriott City Center, 112 Washington Place, Pittsburgh, Pennsylvania, on Monday, February 13, 2017, 9:04 a.m.

* * *

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For the Plaintiffs:
(Via Telephone Conference)

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Also Present: Brad Coble, Videographer

I N D E X

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COMMENCING -- 9:04 A.M.

THE VIDEOGRAPHER: We are now on the record. My name is Brad Coble. I'm the videographer for Golkow Technologies. Today's date is February 13th, 2017, and the time is 9:04 a.m.

This video deposition is being held in Pittsburgh, Pennsylvania, in the matter of In Re Specially Assigned Mesh Implant Case for the Commonwealth of Massachusetts, Middlesex Superior Court. The deponent is Steven Little, Ph.D.

Counsel, please identify yourselves.

MS. KROTTINGER: Katy Krottinger with the Monsour Law Firm for the plaintiffs.

MR. THORNBURG: Daniel Thornburg with Aylstock, Witkin, Kreis & Overholtz for the plaintiffs.

MS. STEELE: Andrea Steele for defendant Boston Scientific.

THE VIDEOGRAPHER: The court reporter is Dutch Cameron and will now swear in the witness.

STEVEN R. LITTLE, Ph.D., having been first duly sworn, was examined and testified as follows:

EXAMINATION

BY MR. THORNBURG:

Q. Good morning, Dr. Little.

A. Good morning.

Q. My name is Daniel Thornburg. I represent the plaintiffs. Do you understand that?

A. Yes.

Q. And we are here to take your deposition as a disclosed expert in the litigation against Boston Scientific concerning its Uphold product. Do you understand that?

A. Yes.

MS. STEELE: Object to form.

Q. Dr. Little, there is an objection so I'm going to make sure I can clarify. Are you offering any other opinions about any other products other than the Uphold?

A. Well, so my report covers polypropylene mesh in general, and I'm here as a general expert in biomaterials and chemical engineering.

Q. Do you know whether or not you are offering any opinions in the Massachusetts State Court litigation regarding any other product besides the Uphold?

A. Well, my -- my review of the literature that I discuss in my report is primarily focused on the

products that are made from the Marlex resin, so they may be applicable to other products besides the Uphold.

Q. You talk specifically about one mesh product in your expert report, and that's the Uphold; correct?

A. Well, I mean, I guess my answer is the same.

Q. Did you name any other products specifically by name, other than the Uphold, in your expert report?

A. I could review my report to see what specific --

Q. Have you -- have you reviewed your report before today?

A. I have reviewed my report before today, yes.

Q. Doctor, let me just try to speed this up. If you turn to page 5 of your expert report --

A. Yes.

Q. -- and you see halfway down the first paragraph before Section III, you say, "Boston Scientific's Uphold device was cleared by the FDA for the treatment of pelvic organ prolapse in 2008."

Do you see that?

A. Yes, I do.

Q. And then you say, "The Uphold device includes a pre-cut piece of Polyform mesh."

Do you see that?

A. Yes.

Q. Okay. In that section, you don't name any other Boston Scientific Corporation mesh device specifically other than the Uphold; correct?

A. In this section here, it appears like the only device that I refer to is Uphold; but I do talk about Polyform, I talk about Marlex, and I talk about polypropylene in the report.

Q. Well, did you talk about the clearance dates for any other Boston Scientific mesh products?

A. No, it doesn't appear that I did, no.

Q. Were you focused primarily on Uphold?

MS. STEELE: Object to form.

A. Well, so what I said before is I -- I reviewed the literature in regard to polypropylene mesh in general. I did not focus any specific review on just something that would pertain to Uphold.

Q. Do you know what other pelvic mesh devices Boston Scientific manufactured for the treatment of

pelvic organ prolapse or stress urinary incontinence?

A. I mean, I'm generally familiar that there are several meshes that are used for pelvic organ prolapse and stress urinary incontinence. The names --

Q. My question was can you name the specific products by name.

A. Sure. I'm -- I think the names are like Pinnacle, Lynx, Solyx, Obtryx; some names that I recall.

Q. Did you look at any internal documents concerning the Pinnacle device?

A. I'm pretty sure that I did review at one point 510(k) -- a 510(k) for the Pinnacle device.

Q. Did you identify that in your expert report?

MS. STEELE: Object to form.

A. I do not know. I could look here to see if I specifically identify that, but I didn't identify everything that I read in this report.

Q. Okay. So everything that you're relying on for your expert report is contained either within the text of your expert report or on your updated reliance list?

A. I believe so, yes.

Q. Would you look at the -- the differences in the material characteristics of the different devices that were manufactured and sold by Boston Scientific for the treatment pelvic organ prolapse and stress urinary incontinence?

A. Well, I've seen the devices before. I did not spend a lot of time looking into the differences between the properties of the various meshes.

Q. Did you look at the -- do you know what the pore size is for the Pinnacle device?

A. I just know that they are Type 1 porous meshes. That's all --

Q. Do you know -- do you know what the pore size is, Doctor?

A. Off the top of my head, no, I just know the categorization.

Q. Do you know what the -- the weight of the -- of the Pinnacle is?

A. No, off the top of my head, I do not.

Q. Grams per square meter, weight, density? No?

MS. STEELE: Object to form.

A. No.

Q. Do you know the material characteristics of the Obtryx device, pore size and weight?

A. Other than what I just specified, no.

Q. So you don't know -- you didn't look at any other -- any internal documents from Boston Scientific that provided you with a description of the specific pore size and specific weight of its pelvic organ prolapse and SUI products; is that correct?

MS. STEELE: Object to form.

A. That information might have been in some of the documents I reviewed. I just don't recall what they are.

Q. Can you identify what document you reviewed that would provide that information?

A. Well, what I said was that I -- it might have been in the documents that I reviewed, I don't remember. For instance, it might be in a 510(k), for instance, that I reviewed.

Q. Okay. So let me try to speed this up. If it's not in any of the documents that are cited in your expert report or on your reliance list, that would mean that you didn't review it; correct?

A. That would probably be correct other than I just saw the devices, but I did not do measurements on the devices, so.

Q. Do you know who Dr. Klinge is?

A. Could you repeat that question.

Q. Are you familiar with who Dr. Klinge is? K-L-I-N-G-E, Uwe is his first name, U-W-E.

A. No, the name doesn't ring a bell.

Q. Are you familiar with Dr. Bernd Klosterhalfen?

A. No.

Q. Did you review or rely on any documents or -- strike that.

Did you review or rely on any publications by Dr. Uwe Klinge or Bernd -- Bernd Klosterhalfen?

A. I don't remember the names.

Q. And if they're not on your expert report, that would indicate that you did not review and are not relying on their publications; correct?

MS. STEELE: Object to form.

A. Well, if it's not in my report or on my materials considered list, then I wouldn't have seen it.

Q. So you wouldn't have known that they are the world-renowned experts in the biomaterial science involve -- concerning the design of mesh devices?

MS. STEELE: Object to form.

A. I'm sorry, could you repeat the question.

Q. So you're not aware that they are considered experts in the field of designing mesh devices for implantation into humans?

MS. STEELE: Object to form.

A. I would not know the source of information that -- that you're referring to or someone's referring to them as that, no, I don't know.

Q. Okay. Now, Mr. Little, you're not a doctor; is that correct?

A. I have a Ph.D.

Q. You're not a medical doctor?

A. I'm not a medical doctor, no.

Q. You're not a veterinarian?

A. No, I am not a veterinarian.

Q. You're not a toxicologist --

A. No.

Q. -- correct? You're not a pathologist?

A. I am not a formally trained pathologist, no.

Q. You don't hold yourself out as an expert in

pathology, do you?

A. I do not hold myself out as an expert in pathology.

Q. You're not an expert in histopathology; correct?

A. No.

Q. You do not have any patents concerning polypropylene mesh devices; correct?

A. No, I don't.

Q. You've never designed a mesh device; correct?

A. I have never designed a mesh device, no.

Q. You've never analyzed explanted pelvic organ prolapse mesh devices used for the treatment of pelvic organ prolapse or stress urinary incontinence; correct?

A. Well, so my review of the literature was an analysis of work that was done on explanted devices, but I have not personally analyzed a mesh device myself.

Q. Mr. Little, that's my point. You've never personally performed any analysis on an explanted polypropylene mesh device; correct?

A. I have not personally analyzed that, but I

must have misheard your question; I just thought you said analyzed.

Q. You're not an expert in the design of polypropylene mesh devices; correct?

MS. STEELE: Object to form.

A. Well, I mean, I guess it depends on what you mean by expert. I have not personally designed a mesh product. I did an analysis of the design of mesh products.

Q. You've never personally designed any mesh device products; correct?

A. No.

Q. You're not an infectious disease doctor; correct?

A. I am not an infectious disease doctor, no.

Q. And in this case, you've not been asked to perform any type of testing on either pristine or explanted mesh devices; correct?

MS. STEELE: Object to form.

A. In this case I was not asked to do testing on any devices, no. Just a literature review.

Q. Have you ever performed FTIR?

A. I have.

Q. Okay. And in what context have you

performed FTIR?

A. Well, I guess I need more information about what you mean by what context.

Q. Well, have you ever -- you -- you said that you have used FTIR before; right?

A. Yes.

Q. And what does that mean, for the ladies and gentlemen of the jury?

A. Well, it's an analysis that's performed that's a chemical-based analysis. It looks for or it can detect the presence of chemical functional groups of a material, specifically on the surface of a material, maybe a little bit less than a human cell thick into the material.

Q. And what's the acronym FTIR stand for?

A. I think it's Fourier transform infrared.

Q. Are there different types of FTIR techniques that can be used when analyzing the chemical makeup of a product?

A. Well, it all operates on the same principle. But you can, for instance, do surface scanning, or you can crush up a sample and put it into a relatively neutral media and analyze it that way.

Q. Have you ever used FTIR on an explanted

polypropylene device?

A. I have not personally done that, no.

Q. Do you own an FTIR machine?

A. I don't personally own a machine. There is a machine available to my lab at the University of Pittsburgh.

Q. If you wanted to use it, would you have the ability to do so?

A. If I -- if I wanted to do that or needed to, I -- yes, I probably would be able to do that.

Q. So you could have looked at explanted polypropylene devices in the context of this litigation, but you haven't; is that correct?

MS. STEELE: Object to form.

A. Well, my understanding is, is that there were not explanted mesh samples in these litigations, but I can say that the literature that I reviewed had a number of different analyses that were performed on polypropylene meshes. And those --

Q. But you --

MS. STEELE: He's still answering.

Q. -- you've never analyzed an explanted polypropylene mesh device. In fact, you've never

analyzed any explanted polypropylene device; correct?

MS. STEELE: Object to form.

A. Well, I -- I performed an analysis of the literature where there were a number of different analyses on and I performed analyses of the data in the -- in those manuscripts on explanted polypropylene meshes. But I have not personally performed a --

Q. I understand you've looked at other people's work. But you haven't performed any work ever in your entire career that involved using FTIR on explanted polypropylene devices; right?

MS. STEELE: Object to form. And I understand you're on the phone, but I'd appreciate if you didn't cut Dr. Little off.

A. So, what you're saying is correct, that I performed my analysis by reviewing a number of studies in the literature that performed tests on explanted polypropylene meshes, but I did not personally perform a study on explanted polypropylene mesh.

Q. My question was you've never looked at -- you've never tested any explanted polypropylene

device ever?

A. And my answer is the same.

Q. The answer is, I'm correct, you've never done that; right?

A. My answer is --

MS. STEELE: Object to form.

A. My answer is that I performed an analysis of the literature and there were a number of different tests on polypropylene meshes, but I have not personally performed a test on an explanted polypropylene mesh.

Q. No, you've never performed an analysis on any explanted polypropylene device, any type of polypropylene device.

MS. STEELE: Object to form.

Q. Right?

A. I have not personally performed testing on explanted polypropylene meshes.

Q. Have you personally performed any testing on any type of explanted polypropylene device?

A. I -- I've answered this question.

Q. Have you ever -- have you ever performed any type of testing, FTIR or otherwise, on an explanted polypropylene suture?

A. No, I have not personally performed testing on an explanted polypropylene suture.

Q. In fact, the first time that you've ever performed any analysis of research done by other scientists on polypropylene meshes is in the context of this litigation; correct?

MS. STEELE: Object to form.

A. I mean, I was aware of the general literature on polypropylene and I understand, generally, its use in biomaterials, and I wouldn't say that it's the first time I ever thought about polypropylene or polypropylene meshes is in the context of this litigation.

Q. My -- my 11-year-old son understands all that generally. That doesn't make him an expert; right?

MS. STEELE: Object to form.

A. I'm sorry, is that a question?

Q. Yep.

A. Could you repeat the question, please.

Q. Just because somebody has a general understanding of -- that polypropylene devices have been used in medicine and has a general understanding of some of the publications, that

doesn't make that person an expert?

MS. STEELE: Object to form.

A. Well, I mean I guess it depends on how you're defining expert. I would say that I am an expert in biomaterials and in chemical engineering. My focus specifically in that area is on degradable materials, which are materials that degrade in the body.

Q. Let me ask you this question. Other than this litigation, have you ever consulted with a medical device manufacturer on the design of a mesh implant?

A. No, I have not personally done that.

Q. Have you ever consulted with any medical device manufacturer on the design of any polypropylene medical device?

A. No, again, not on -- specifically on a polypropylene device. My -- my focus area is on materials that degrade in the body.

Q. You've never observed the implantation of a surgical mesh device; correct?

A. No, I have not.

Q. Is this the very first time that you have offered testimony as an expert regarding

polypropylene material that was implanted in a human?

A. Well, I've submitted some reports in this case, and this is the first time I'm being deposed in this case. I have not performed or given testimony on polypropylene meshes before this case, no.

Q. Outside of the context of the Boston Scientific mesh litigation, is this the first time that you've testified as an expert regarding polypropylene material that's been used as an implant in the human body?

A. Yes.

Q. Prior to your involvement in the Boston Scientific litigation, have you ever tested polypropylene for degradation?

A. Specifically tested it for degradation, no.

Q. Have you ever performed any preclinical testing of polypropylene mesh implants?

A. No, I have not.

Q. Have you ever performed any preclinical testing of any type of polypropylene product?

A. I have not performed preclinical testing on specifically polypropylene product, no.

Q. And do you know what I mean when I -- if I use the term or the terminology "preclinical"; do you know what that means?

A. Yes, I do.

Q. And can you explain that to the ladies and gentlemen of the jury.

A. Well, by preclinical, I think -- when I think preclinical, I think that the testing is performed to determine efficacy or safety in an animal model, and it could be performing an analysis of extracted products, those kind of things.

Q. Have you ever analyzed -- so when I use the phrase "preclinical," you'll understand I'm talking about animal studies, and when I use the word "clinical," I'm talking about human studies?

A. Yes.

Q. Have you ever analyzed any explanted polypropylene product from any preclinical study?

A. No, I've not.

Q. Have you ever performed any post-marketing testing of any mesh implants prior to this litigation?

A. Could you repeat the question. I'm sorry, I

didn't hear it.

Q. Have you ever performed any post-marketing testing of mesh implants prior to this case?

MS. STEELE: Object to form.

A. No, I haven't.

Q. Have you ever performed a failure analysis of a polypropylene device?

A. I have not personally performed a failure analysis of a polypropylene device, no.

Q. Have you ever performed a failure analysis of a polypropylene suture?

A. No.

Q. What does peer-reviewed publication mean to you?

A. It means that a work was submitted to a journal; the editor sent it for peer review, received some comments, usually from reviewers; the manuscript is reviewed according to the comments; and then is evaluated again until the editor believes that the reviewers' comments had been addressed, at which time it's published.

Q. And you've published some peer review -- you've got -- strike that.

You have some peer-reviewed

publications throughout your career; correct?

A. Yes.

Q. But you have never published any articles in a peer-reviewed journal concerning polypropylene degradation; correct?

MS. STEELE: Object to form.

A. No, I've -- I haven't performed testing on polypropylene degradation personally, no.

Q. In fact, you have never published in the peer-reviewed literature on the subject of polypropylene even generally; correct?

A. Even generally. I mean, I could look to see if generally the class of materials that I have talked about would include it or specifically it's mentioned. Again, my focus of my particular work is on degradable materials.

Q. You've never studied the biocompatibility of the polypropylene mesh for the human tissue; correct?

A. I don't know. I think I probably would have -- regarding studied it, I mean, I'm aware of it; it would have been in my education. I have not published research articles on that topic, myself, no.

Q. Let me ask a better question. You've never personally performed any biocompatibility studies of polypropylene devices; correct?

A. No. Personally, no.

Q. And that would include polypropylene mesh; correct?

A. Correct.

Q. And that would include polypropylene sutures; correct?

A. Personally, no.

Q. And that would include any polypropylene medical device; correct?

A. Yes.

Q. You've never published personally on the subject of biocompatibility of polypropylene mesh for use in the human body; right?

A. I have not published specifically on the topic you just stated, no.

Q. You've never held yourself out as an expert in the biocompatibility of polypropylene devices; correct?

MS. STEELE: Object to form.

A. Well, I think I'm -- I'm -- I'm pretty informed on biocompatibility of materials. I

understand biocompatibility concerns with polypropylene mesh. I've not published specifically on the topic of polypropylene biocompatibility, no.

Q. Well, in fact, prior to your involvement in the Boston Scientific litigation, not a single device manufacturer has come to you and asked you to perform biocompatibility testing of their polypropylene devices; correct?

A. No, companies have not come to ask me to perform studies on biocompatibility of polypropylene.

Q. You've never spoken or presented on the topic of polypropylene mesh prior to being retained by the defendants in this case; correct?

A. No, I've not spoken on that specific topic, no.

Q. You've never taught or lectured on the subject of polypropylene; correct?

A. No, I'd say, again, my -- my focus is on biomaterials, chemical engineering; I do talk about a biocompatibility, but I have not specifically given a talk on polypropylene mesh biocompatibility.

Q. In fact, you have no understanding whatsoever of the biomechanical properties of the pelvic floor?

A. No understanding whatsoever? I'd say that's probably wrong.

Q. What's the tensile strength of pelvic tissue surrounding the -- the urethra?

A. I don't know.

Q. What pelvic muscles -- what are the names of the pelvic muscles in the -- in the pelvic area of a woman called?

A. I don't know.

Q. Where's the apex located?

A. I don't know. Again, my expertise is in biomaterials and chemical engineering.

Q. Where's the introitus located?

A. I don't know.

Q. You're not a urogynecologist; correct?

A. No, I'm not.

Q. You don't hold yourself out as an expert on the female pelvic anatomy, do you, sir?

A. No.

Q. Do you know how many women nationwide have filed lawsuits against Boston Scientific concerning

its pelvic organ mesh devices used for the treatment of pelvic organ prolapse or stress urinary incontinence?

MS. STEELE: Object to form.

A. I'm not aware of the number, no.

Q. Have you personally spoken with any patient or individual who has -- who has suffered harm as a result of being implanted with a Boston Scientific pelvic organ device?

MS. STEELE: Object to form.

A. No, I haven't.

Q. Have you ever -- have you treated any patients? I mean, you're not a medical doctor; right?

MS. STEELE: Asked and answered.

Q. Right, Doctor?

A. No.

Q. So you've never spoken to any patients about the lifelong consequences that they've experienced after having Boston Scientific's either sling or pelvic organ prolapse device implanted; correct?

MS. STEELE: Object to form.

A. No, I'm not a medical doctor.

Q. And the opinions that you're offering in

this case in the Boston Scientific litigation concerning degradation of polypropylene mesh implants have never been published by you in any peer-reviewed journal; correct?

A. No.

Q. No -- no, meaning I'm correct?

A. Yes, I have not published my opinions in this case, no.

Q. Now, Dr. Little, you've brought some documents with you today that are -- that you believed are responsive to the Notice of Deposition Duces Tecum?

A. I brought some documents, yes.

Q. Let's go ahead and mark as Exhibit No. 1 the notice of your deposition.

COURT REPORTER: Okay. It's marked.

(Little Deposition Exhibit 1 was marked for identification.)

BY MR. THORNBURG:

Q. Dr. Little, have you seen the notice of your deposition before?

A. Yes.

Q. And when were you -- when were you provided the -- your deposition notice?

A. I'm pretty sure it was last week.
Q. Okay. And if you go to the Appendix A -- I'm sorry, Schedule A, page 5, of the deposition notice. Are you there, Doctor?
A. I am.
Q. Okay. Did you review Schedule A prior to appearing for your deposition today?
A. Yes.
Q. And did you provide a -- strike that.
Let's go ahead and mark as Exhibit No. A the invoices that you brought with you related to the work you performed in the Boston Scientific litigation.
MS. KROTTINGER: Exhibit No. 2, you mean?
(Little Deposition Exhibit 2 was marked for identification.)
Q. Doctor, you're being paid $850 per hour; is that correct?
A. Yes.
Q. And that's to offer opinions on behalf of Boston Scientific?
MS. STEELE: Object to form.
A. It's to offer my opinions in the areas that

I refer to in my report.

Q. Concerning the degradation of polypropylene; correct?

A. Well, I do discuss that topic. I discuss some other topics as well in my report.

Q. One of the opinions that you're being asked to offer your opinions on relates to the propen- -- propensity for Boston Scientific's Marlex polypropylene mesh device to degrade; correct?

MS. STEELE: Object to form.

A. Well, it's my opinion that they -- they don't degrade.

Q. But it's your opinion after being paid $850 per hour by Boston Scientific that Boston Scientific's Marlex meshes do not degrade; correct?

MS. STEELE: Object to form.

A. Well, if you're implying that they're paying me to say that it degrades (sic), that would be wrong.

Q. Well, they are -- they are paying you; right?

A. Yes, they're paying me to do my analysis and work.

Q. They're paying you $850 per hour to do your

analysis and work; correct?

A. Which is a standard rate that I have for everyone that I do consulting for.

Q. $850 per hour; correct?

A. Yes.

Q. And despite the fact that you've never performed any type of analysis, you've never lectured on polypropylene, you've never looked at explanted polypropylene devices, you've never performed biocompatibility studies on Marlex mesh, you were asked to offer opinions in this case; correct?

MS. STEELE: Object to form.

A. Yeah, I mean, if your implication is that I need to have done all of that to provide an opinion on the biocompatibility and degradability of these polymers, that's wrong.

Q. The jury will decide that, won't they?

MS. STEELE: Object to form.

Q. You understand that it's the jury's job to decide the facts in this case and to weigh the credibility of the witnesses that are called to testify at trial; right?

MS. STEELE: Object to form.

Q. You understand that, Dr. Little?

A. That -- that may be right. I know the judge is involved in this. I -- I don't know. It's up to you guys. I'm not a lawyer.

Q. You understand that you're providing deposition testimony today under oath?

A. Yes.

Q. And that you have to provide truthful and accurate information during your deposition today?

A. Yes.

Q. And do you understand that your deposition today has the same force and effect as if we were sitting in a courtroom in front of a judge and in front of a jury?

MS. STEELE: Object to form.

Q. Do you understand that, Dr. Little?

A. I guess I -- that sounds like it could be generally true. I'm not a lawyer, so I don't know -- I do know that deposition testimony can be played in a courtroom. I do not understand the details of the force and other things that you specified.

Q. You understand that you are subject to the penalties of perjury today during your deposition

the same as you would be in front of -- if you were sitting in front of a jury or in front of the court?

MS. STEELE: Object to form.

A. I do believe that's true, yes.

Q. How much -- I don't -- obviously, I'm not there in person. You're getting paid $850 per hour. How many hours have you invoiced, and what is the total amount of your invoices?

A. I haven't gone through and added up all of the hours. I could do that if you'd like me to right now. The amount total over the period of time is about 300,000; since April, so ten months.

Q. April 2016?

A. Yes.

Q. So in the ten months since you've been retained, you've invoiced $300,000?

MS. STEELE: Object to form.

A. Yes.

Q. And when does the invoice date end?

MS. STEELE: You can look at the --

A. The -- the most recent invoice was just -- in January.

Q. Have you performed additional work in this

case since January?

A. Just preparing for this deposition.

Q. How much time have you spent preparing for this deposition?

A. I don't have the numbers on me right now.

Q. Can you give me an approximation?

A. I don't think so. I mean, I've spent the last --

Q. I'm entitled to a fair estimation, Doctor.

A. Okay. I've spent the last couple of weeks looking at materials, I might say more heavily over the last week. I mean, I would -- if I could try to look and see when I tried to prepare for the last deposition that was moved, I mean, maybe on the order of like 40, 50 hours.

Q. So you're owed, in addition to the $300,000, an additional 12 or $15,000?

MS. STEELE: Object to form.

Q. Approximately.

A. Yeah, I don't -- again, this is a very rough estimate.

Q. Doctor, you don't --

(Telephone beeps.)

Q. You don't hold -- strike that.

MS. KROTTINGER: Did someone else --

Q. You will not offer any opinions concerning pathology; correct?

MS. STEELE: Object to form.

A. Well, what I'd say is that in -- in this report, I -- there are manuscripts where some, for instance, histology slides are given. I don't hold myself out as a expert in pathology, but I did review that data, and I'd say it's part of my opinion.

Q. But you're not an expert in pathology.

A. I don't hold myself out to be an expert as a pathologist, no.

MS. KROTTINGER: Who joined the phone?

Q. Despite that --

MS. KROTTINGER: Hold on, Dan. Somebody joined.

MR. THORNBURG: Hello? Did somebody join? Hello?

MS. KROTTINGER: Is anybody else on the phone?

MS. STEELE: Do we have a way of seeing how many people are connected?

MR. THORNBURG: Are we off the record?

THE VIDEOGRAPHER: Going off the record. The time is 9:50 a.m.

* * *

(Whereupon, an off-the-record discussion was held.)

* * *

THE VIDEOGRAPHER: We're going back on the record. The time is 9:51 a.m.

BY MR. THORNBURG:

Q. Doctor, at trial you're not going to suddenly attempt to hold yourself out as an expert pathologist; correct?

MS. STEELE: Object to form.

A. No. I'm not going to say that I'm an expert in pathology as a -- as a formally trained pathologist. I will -- I may refer to data that is in the literature in my analysis.

Q. At trial in this -- in any of these cases in Massachusetts or elsewhere, you're not going to suddenly hold yourself out as an expert in the female pelvic anatomy.

MS. STEELE: Object to form.

A. I'm -- I don't think that I'm going to be holding myself out as an expert in that, no.

Q. Well, look, this is my only time to depose

you, so I need to know now whether or not you're going to offer opinions as an expert urogynecologist.

A. No, I'm not.

Q. You're not going to suddenly show up at trial and hold yourself out as an expert in the design of polypropylene mesh devices for the treatment of pelvic organ prolapse or stress urinary incontinence; correct?

MS. STEELE: Object to form.

A. Other than what is in my report here that I can comment on with regard to biomaterials and chemical engineering, I'm not going to be holding myself out as an expert in specifically the design of materials for pelvic organ prolapse or stress urinary incontinence.

Q. Well, you're not going to show up at the trial in this case and offer any opinions, for example, of bridging fibrosis? Do you know what bridging fibrosis is?

A. I'm not going to be providing opinions on that, no.

Q. Do you know what -- do you know what bridging fibrosis is?

A. The name -- the name is not ringing a bell.
Q. You're not going to show up at trial in any of these cases and suddenly hold yourself out as an expert in the material requirements for manufacturing a pelvic organ prolapse or stress urinary incontinence mesh device; correct?
MS. STEELE: Object to form.
A. You may need to be more specific in terms of what you mean by requirements.
Q. Well, are you -- have you reviewed any materials in preparation for the deposition or when you drafted your expert report concerning the design requirements for the manufacture of pelvic organ prolapse or stress urinary incontinence devices?
MS. STEELE: I object to form.
A. I'm sorry, could you repeat the question.
Q. I'll ask Madame Court Reporter if she can read back the question.
(Whereupon, reporter read pending question.)
A. Well, I mean, I can say that I reviewed materials related to classification of the systems, pore sizes, and things like that, and I generally know the function of the devices, but I'm -- if

you're referring to like design specifications and tolerance levels, no.

Q. You're referring to the amide classifications from 1997?

A. Yes.

Q. You haven't reviewed the publications from Klinge or Klosterhalfen; right?

A. Not that I recall.

Q. And, therefore, you have not relied on or even considered the classifications described by or the design requirements related to pore size and weight authored by Drs. Klinge and Klosterhalfen; correct?

A. Well, so I'd say is -- again, I don't remember those names. If it's not in my materials considered list, then I wouldn't have seen those. But I would just say that I -- I understand the reasoning behind the Amid classification. If there's another reason in the other ones, it would be whether or not I -- I mean, I don't remember that.

Q. If it's not on your list, you didn't consider it; correct?

A. Yes.

Q. Do you know how many publications have been authored by Drs. Klinge and Klosterhalfen concerning the pore size and weight necessary for manufacturing a biocompatible mesh device?

A. No, I don't.

Q. Have you ever heard the phrase "scar plate"?

A. I have heard the phrase. It's -- I guess I've heard the phrase more in the context of this litigation. I see it being used quite a bit by -- by plaintiffs.

Q. Do you know the difference between scar net and scar plate?

A. I would say that I -- I know what scar tissue is, but the difference between the two specific terms you just said, no.

Q. Do you have any understanding whatsoever concerning the relationship between pore size, scar net and scar plate?

A. No.

MS. STEELE: Object to form.

Q. Can you repeat your answer, please.

A. No.

Q. So you will not suddenly appear at trial in any one of these Boston Scientific cases and

suddenly have an opinion concerning pore size and its relationship between scar net and scar plate; correct?

MS. STEELE: Object to form.

A. No.

Q. No, you will not show up at trial, correct, with those opinions; correct?

A. No, I'm not going to talk specifically about what you said. To my understanding.

Q. And when was the first time you met Mrs. Steele?

MS. STEELE: Ms.

MR. THORNBURG: Sorry, Ms. Steel, I apologize for that.

A. I believe, I mean, it would have been midyear last year.

Q. Have you ever been retained by any defendant who was represented by Shook, Hardy & Bacon prior to the Boston Scientific mesh litigation?

A. No.

Q. In your expert report you list a number of depositions you've provided -- testimony provided within the last five years.

I think 3. We -- we might as well

mark as Exhibit 3 your expert report.

(Little Deposition Exhibit 3 was marked for identification.)

Q. Are you there, Dr. Little?

A. Yes.

Q. All right. You have Shire Development LLC, Incorporated -- I'm sorry, et al. versus Watson Pharmaceuticals, Incorporated, et al. listed as bullet point No. 1; correct?

A. Yes.

Q. And who were you retained by in that litigation?

A. It was counsel for Shire.

Q. And is Shire a pharmaceutical company?

A. Yes.

Q. And then bullet point No. 2, it says -- you have listed Salix Pharmaceuticals Incorporated, et al. versus Lupin Ltd., et al. And who were you retained by in that litigation?

A. That was Salix, counsel for Salix.

Q. Okay. And who was counsel for Shire Development?

A. Counsel for Shire Development I believe is Frommer Lawrence & Haug.

Q. Okay. And for Salix, who was counsel for them?

A. I believe it was Womble Carlyle Sandridge & Rice.

Q. And again, Salix Pharmaceuticals is a pharmaceutical company; correct?

A. Yeah, I mean, every name on this list, both plaintiffs and defendants, are pharmaceutical companies.

Q. And is it fair to say that you've only been retained to offer expert opinion testimony on behalf of lawyers representing corporate defendants?

MS. STEELE: Object to form.

A. Well, yes, so the work that's on this sheet is -- is pharmaceutical patent litigation, so all defendants and plaintiffs are pharmaceutical companies.

Q. So it's fair to say that in the last five years at least you've only been retained by plaintiffs or defendants who were corporate defendants or plaintiffs?

A. Um, I guess by the nature of doing pharmaceutical patent litigation, that's -- that's

a requirement, so yes.

Q. Have you ever been or have you ever -- ever offered opinions where you've been retained by a plaintiff who has alleged personal injury as a result of a pharmaceutical or medical device product?

A. Again, I've -- I've only done patent litigation, so no.

Q. So the answer to my question is, no, you've never offered opinions on behalf of a plaintiff who has alleged personal injuries as a result of a pharmaceutical or medical device product; correct?

A. Um, so what you're saying is right. I've only done, up to this point, pharmaceutical patent litigation.

Q. Have you ever done any type of medical device litigation? Let me ask better question.

Have you ever been involved in any type of medical device litigation?

MS. STEELE: Object to form.

A. I've only worked on patent litigation so far. So this is the first time I've done this.

Q. Pharmaceutical patent litigation; correct?

A. Yes. Correct.

Q. And in the bullet point 1, the first bullet point, Shire Development versus Watson Pharmaceuticals, what type of product was involved in that litigation?

A. It was a -- a pharmaceutical product so a drug.

Q. What drug?

A. I think it was the Lialda product.

Q. And that did not involve the issue of polypropylene biocompatibility or degradation; correct?

A. No, it was a solid oral dosage form.

Q. And that's the same for Salix Pharmaceuticals?

A. That product was different. I can't remember the name of it off the top of my head, I'm sorry.

Q. Another product but it didn't involve polypropylene; correct?

A. I don't recall all of the specifics as to what's in it.

Q. Do you know if polypropylene is used by pharmaceutical companies?

A. It may be under circumstances. I don't know

if I can make the statement that -- if it is or isn't or I'm even allowed to say what's in these products.

Q. Salix Pharmaceuticals Incorporated, is that the same drug that was -- I'm sorry, bullet point 3.

Hello?

A. Yes?

Q. Dr. Little, did you hear my question?

A. I did not, I'm sorry.

MS. STEELE: I think we were looking at bullet point 3, and you were asking if it was the same drug.

Dan, can you --

Q. Yeah, sorry. My question is, for bullet point 3, Salix Pharmaceuticals versus Novel Laboratories, is that -- did that involve the same drug as bullet point No. 2?

A. Yeah, I mean, I can't remember specifically the name of the drug.

Q. Was there -- was -- was there a polymer used in the drug?

A. I don't know if I'm allowed to say what's in these drugs.

Q. I'm not asking you for the specific ingredient; I'm asking you if there was any polymer, any type of polymer whatsoever, as an ingredient within those drugs.

A. I don't think I'm allowed to say that.

Q. Is that -- will that be your answer for all bullet -- bullet points on page 3 and page 4?

A. Yeah, I would need to talk to my counsel for these cases to determine whether or not I'm allowed to say the composition of the drugs. I think the answer would be no.

Q. You believe that whether or not a polymer was used in any of these drugs would be proprietary information that's subject to some type of confidentiality provision?

A. I would need to ask to be sure.

Q. So today you will not provide that information?

A. Today, I don't know if I'm allowed to provide the information, so I'm not going to.

Q. How -- for how many years have you been offering expert opinion testimony where you've been retained by counsel or a party who was a corporate plaintiff or defendant?

A. I'd say maybe five years or so.

Q. So this list on page 3 and 4 includes, to the best of your knowledge, all of the cases where you've been retained as an expert witness on behalf of a corporate defendant or plaintiff?

A. Yes.

MS. STEELE: Object to form, retained. Testified.

A. This list, to the best of my knowledge, includes all of the testimony that I've provided. And again, it's in -- it's in pharmaceutical patent litigation.

Q. When I use the -- the term polyofelin, (sic), do you know what that means?

A. Polyolefin yes.

Q. Yes, polyolefin. You have an understanding of what that means?

A. Yes.

Q. What is a polyolefin?

A. Polyolefin is a -- is a polymer that's made from -- it's a hydrocarbon chain, a straight hydrocarbon backbone chain. Can have pendant groups on it, but it's carbon and hydrogen.

Q. What -- what types of polymers fall within

the polyolefin group?

A. What types of polymers? I mean, it's polyethylene.

Q. The specific names of them, yes.

A. Right. Polyethylene and polypropylene are the two that are the most widely used; the production is mainly focused on those two. But there are others that have different side chains so you can have a longer side chain or branch side chain.

Q. Have you ever offered any expert opinions or been retained as an expert concerning polyethylene?

A. Retained as an expert regarding polyethylene? Again, I don't know if polyethylene is contained in any of these other formulations. Specifically, only talking about polyethylene, no.

Q. Have you ever consulted with any medical device company concerning designing any type of medical device using polyethylene?

A. Not that I'm aware of, no.

Q. Have you ever been -- have you ever consulted with any medical device manufacturer concerning designing any product made out of any type of polyolefin?

A. Not that I'm remembering right now, no.
Q. Have you ever performed any type of testing whatsoever to determine the stability or degradability of any type of polyolefin?
A. I have not personally performed testing on stability/degradability of polyolefins.
Q. Have you performed any type of testing concerning the stability or biodegradability of any type of polymer?
A. Yes.
Q. What polymer?
A. Well, the ones that I focus on the most are polymers that degrade in the body. So polyesters, polyanhydrides, ortho esters, for instance.
Q. I'm sorry, that was polyesters?
A. Uh-huh.
Q. Orthro -- ortho esters?
A. Yep.
Q. What else?
A. Polyanhydrides.
Q. And those do not belong to the polyolefin group of polymers; correct?
A. No.
Q. And have you ever looked at explant --

strike that.

Have you ever studied explanted polyesters, ortho esters, or pol- -- polyanhydrides?

A. Yes.

Q. And what were the names of those products?

A. Well, they were in preclinical studies, so they are systems that we have been designing. And we would do, at times, histology or removal, and observe the properties.

Q. Did you ever perform FTIR on explanted polyesters, ortho esters, or polyanhydrides?

A. We might have, yes. I don't recall a specific instance, but we may have.

Q. Have you performed GPC studies on polyesters, ortho esters, or polyanhydrides?

A. Probably, yes.

Q. Have you performed PyMS on polyesters, ortho esters, or polyanhydrides?

A. That specific technique, I don't recall.

Q. Do you know what I mean by the acronym DCS -- DSC?

A. DSC, yes.

Q. What does DSC stand for?

A. That's differential scanning calorimetry.

Q. Have you used that technique in analyzing polyesters, ortho esters, or polyanhydrides?

A. I've used the technique. I don't recall specifically what materials it was on. But yes, I have experience with the technique.

Q. And that's a technique -- basically, a technique of thermal analysis?

A. Generally, yes.

Q. Looking at the crystallinity of a type of product?

A. You can use it to determine the amount of crystallinity in specific circumstances, yes.

Q. What other thermal techniques have you used to analyze the stability or degradability of polyesters, ortho esters, or polyanhydrides?

A. You specifically saying thermal techniques?

Q. Yep.

A. Well, I mean, you can do, for instance, like, melting point analysis.

Q. Right.

A. And DS --

Q. And have you done a melting point analysis on explanted polyesters, ortho esters, or

polyanhydrides?

A. We might have, I don't recall.

Q. Would you feel comfortable doing a melting point analysis of a polyester, ortho ester, or polyanhydrides sitting here today?

A. Well, sitting here today, I mean, if you're asking me could I determine the melting point, I'd have to look into it. But I mean, I've done melting point analysis before.

Q. What other stability techniques have you used in your experience?

A. Stability techniques. Well, I mean, I have -- I have seen EDS performed, x-ray diffraction performed.

Q. Have you ever performed it yourself?

A. I have performed x-ray diffraction before. I've been involved in testing that was done on EDS.

Q. Have you ever performed it yourself?

A. I believe so, yes.

Q. Okay. What about scanning electron microscopy; is that a technique that you've done before?

A. Yes.

Q. Okay.

A. That's visual analysis, not thermal.

Q. Right. And what was your -- what was the purpose of performing a visual analysis of any product you analyzed in your -- in the past?

A. Typically, you use it to examine surface characteristics. So you're looking for things like roughness patterns, if, for instance, you wanted to design that. Sometimes you can use it to determine integrity of very thin things because you're looking at the, just the surface.

Q. So you looked at it to look for morphological characteristics, and what was your end goal in using SEM or SEM EDS techniques?

A. Right, so it's just to determine, for instance, integrity. So if you're making something that you would hope have a smooth surface, you can and look and see if, for instance, the surface isn't -- isn't smooth or doesn't have integrity or something like that.

Q. So you've used SEM to reach a conclusion about whether or not a particular product met the -- your expectations of integrity.

MS. STEELE: Object to form.

A. I think that's right, yes.

Q. For example, if you were looking at a product that should have a smooth surface but under scanning electron microscopy it was cracked, that would be something that would concern you because it didn't meet your expectation.

MS. STEELE: Object to form.

A. Well, I think that -- I've done this before, for instance, like after fabrication. So you fabricate the device and you look at it and you see whether or not it has the surface characteristics that you -- you'd like. I mean, you're mentioning cracks which is a major point of analysis for a lot of the literature in this specific case. I would say that I would not rely on it heavily if you're talking about a material that's been explanted and not cleaned.

MS. STEELE: Are you good?

Q. Are you familiar with the ASTM guidelines?

A. I am familiar with some in my career. Off the top of my head, I'm not saying that I would be aware of all of them.

Q. Did you review or consider, and offer any opinions in this case, the ASTM guidelines concerning the analysis of explanted polypropylene

devices?

A. I mean, I have reviewed the document relating to the ASTM procedures for explanted materials. Yes, I have reviewed that.

Q. Have you reviewed the materials for the ASTM guidelines -- strike that.

When was the last time you looked at the ASTM guidelines concerning explanted materials?

A. Probably within the last several months.

Q. Okay. Did you review them in conjunction with your preparation for providing testimony in this case?

A. I believe so, yes.

Q. Okay. Did you list it on your material reliance list?

A. I don't recall if it's on there.

Q. The only protocol that you -- that physically accept as a valid protocol for cleaning explanted polypropylene materials in the -- in your expert report is the protocol used by Dr. Thames; correct?

MS. STEELE: Object to form.

A. Well, there is a protocol that is referred to by Dr. Thames. But I do recall there being some

cleaning methods used in manuscripts prior to that point where you could see material actually being cleaned off. But specifically referring to the protocol, that's the focus of Dr. Thames' article.

Q. Did you compare Dr. Thames' explant cleaning protocol with the protocol outlined by the ASTM?

A. Did I compare it? I don't recall if I did a direct comparison. There was nothing that stood out to me as odd in it, if that's what you mean.

Q. You consider the ASTM guidelines to be authoritative?

A. Um, well, I would say that it's an agreed upon method for certain circumstances; but what I would say is that if you were to perform that and you were to determine that the material's not cleaned off appropriately, then you would need to do something else.

Q. Did you -- but in any case, you did not compare Dr. Thames' cleaning protocol to that of the ASTM protocol; correct?

A. I mean, I don't know what you mean by compare. I remember some things about --

Q. Look at them side-by-side and consider the ASTM protocol when you offered opinions about

Dr. Thames' protocol?

A. Well, I -- what I would say is that there was nothing that concerned me about Dr. Thames' protocol from what I recall in the ASTM procedures.

Q. Did you -- my question is did you specifically set out to compare the protocol outlined by ASTM to the protocol used by Dr. Thames?

A. Did I set out to compare them?

I would say that after I read Dr. Thames' article, I didn't feel the need to go back and compare them, no.

Q. So the answer is you did not compare the two; correct?

A. I did not put them side-by-side and go through a comparison because I didn't have a concern to do that, no.

MS. STEELE: Are you good or do you want a break or --

THE WITNESS: I'm fine.

MS. STEELE: Okay.

Q. I hate to go back, but I'm going to go back real quick. You can confirm for me that in every case where you've provided testimony, you've done

that on behalf of a corporate party to a lawsuit; correct?

A. Yeah, I mean, I've already answered this question. I mean, essentially, what I've done up to this point is pharmaceutical patent infringement; so no matter who I would have worked for, it would have been for a corporate entity.

Q. A hundred percent of the time you have agreed to be hired as a consultant or an expert witness on behalf of corporate parties in a lawsuit; correct?

A. I mean, my answers are the same.

Q. But it's a yes or no answer. A hundred percent of the time you've been retained by a corporate party in a lawsuit; correct?

A. Right.

MS. STEELE: Asked and answered.

A. By definition, working in pharmaceutical patent litigation, yes.

MR. THORNBURG: I'm going to strike everything except for your answer yes.

MS. STEELE: Oppose motion to strike.

Q. Has any court ever excluded you as an expert witness before?

A. No.
Q. Have your opinions ever been limited?
A. Could you explain what you mean by that.
Q. Well, did you have opinions about A, B, C, D, and E but by the time you were able to testify at trial, the Court limited you to opinion A and B?
A. No.
Q. Now, regarding your reliance list, is it fair to say that the materials that you've referenced on your reliance list are materials that were -- were provided to you by Boston Scientific's attorneys?
MS. STEELE: Object to form.
A. No, I mean, I -- I looked up a good number of those on my own. Some were provided, and at times it was because I was told that I, you know, should see something. At other times it was because I requested to see it and then counsel provided it.
Q. Is it fair -- so let's talk about that.
Did Boston Scientific provide you with any depositions that have been taken for you to review in rendering your opinions in this case?
A. Depositions, I reviewed deposition

testimony, for instance, by Dr. Mays.

Q. Okay. And that would have been provided to you by Boston Scientific's counsel; correct?

A. Yes.

Q. Did you review expert reports?

A. Um, I believe I reviewed, yes, Dr. Mays' expert report.

Q. Okay. And that would have been provided to you by Boston Scientific's counsel; correct?

A. Yes.

Q. The internal documents that are listed in your expert report or within your reliance list, those were -- were chosen by Boston Scientific and provided to you to rely on; correct?

A. The -- what again on the list are you referring to?

Q. Internal corporate Boston Scientific documents.

A. Right. So, you know, some of those things I would have asked for; some of those things were provided to me.

Q. Did you ever ask for any materials that Boston Scientific was unable to provide to you?

A. No.

Q. Did you ask Boston Scientific to provide to you all of their validation studies concerning the appropriateness of the antioxidants that were used in the Marlex resin or Marlex mesh product?

MS. STEELE: Object to form.

A. Specifically those documents related to that topic, I can't remember.

Q. Do you know what I mean by validation studies?

A. Yes, but I -- I don't remember about when I read those and what the conversation was surrounding them.

Q. Well, have you ever heard of the phrase "design validation"?

A. I have heard of it, yes.

Q. Explain to the ladies and gentlemen of the jury what your understanding of design validation is in the context of designing a medical device like Boston Scientific's mesh product.

A. Yeah, I've heard this term. I'm not an expert on the details of that.

Q. Okay. Did you -- did Boston Scientific provide to you any of their design validation internal corporate documents?

A. I don't remember. I'm sorry.

Q. Did you ask for them?

A. I -- I don't think so, no.

Q. Do you know how Boston Scientific came to decide that Irganox would be an appropriate antioxidant to use as a permanent implantable device?

MS. STEELE: Object to form.

A. How that happened, no. I'm not aware of it.

(Telephone beeps.)

Q. Have you ever studied the suitability of Irganox as a --

(Background conversation)

MS. STEELE: Hi, I think we --

MR. THORNBURG: I'm trying to take a deposition and I'm being interrupted.

MS. STEELE: Those people aren't in our room, so we're not sure who just joined the phone. It beeped.

MR. THORNBURG: Hello?

THE VIDEOGRAPHER: Going off the record at 10:32 a.m.

* * *

(Whereupon, an off-the-record discussion was held.)

* * *

THE VIDEOGRAPHER: Going back on the record. The time is 10:33 a.m.

BY MR. THORNBURG:

Q. And if the court reporter could just read back the question, whatever part of it she got for me.

(Whereupon, reporter read pending question.)

A. No, I've not.

Q. I don't think I was actually finished answering -- or asking the question. So no -- no, you have not looked at any internal documents to determine how Boston Scientific determined that Irganox was the appropriate stabilizer to use in its pelvic organ prolapse and SUI products; correct?

MS. STEELE: Object to form.

A. Not that I can recall, no.

Q. Did you ask for those documents?

A. No.

Q. Have you specifically personally studied the suitability of Irganox as a stabilizer in implantable medical devices?

A. I have not personally done that, no.

Q. Have you ever studied the propensity of Irganox to leach out of the polypropylene fibers after implanted in either a clinic -- clinical or preclinical environment?

A. No, I've not personally done that.

Q. Have you studied in any way the suitability of Irganox as a stabilizer in terms of preventing or retarding or -- or -- strike that.

Have you studied the suitability of using Irganox as a stabilizer in any medical devices?

A. No, I have not.

Q. Before you were involved in this litigation, did you -- have you conducted any research on Irganox and the suitability of Irganox as a stabilizer in medical device products?

A. Specifically, no, I have not.

Q. Prior to this litigation, did you have any understanding of Irganox as a stabilizer?

A. Yeah, I mean, I -- I understand the general classification of stabilizers that -- that we're talking about here, these primary stabilizers. But I did not, for instance, obtain that specific stabilizer and study it, no.

Q. You understand -- do you have an understanding that not all stabilizers are the same?

A. Well, I mean, a different stabilizer has different chemical structure, for instance, yes.

Q. Some -- some will leach out more readily in a water environment than others; correct?

MS. STEELE: Object to form.

A. I'm -- you know, I'm not providing opinions on that. I'd have to look into it.

Q. Do you know what the ion bond is of Irganox?

A. I -- no, I don't.

Q. Do you know what Irganox would look like in an FTIR of a polypropylene implant -- I'm sorry, of a pristine polypropylene Marlex mesh device?

MS. STEELE: Object to form.

A. I mean, offhand, right now I couldn't recite what the spectrum would be. I mean, I could look at the -- the chemical groups and go through an analysis. You can even put something like that -- the most easy thing to do is put it into a program and it generates what that would look like.

Q. But you haven't done that; right?

A. What the FTIR spectrum specifically would

be? No.

Q. So you can't offer any opinion about whether or not a -- Boston Scientific's pristine Marlex mesh devices under an FTIR analysis can detect Irganox or an Irganox spectrum?

MS. STEELE: Object to form.

A. You're asking me if I could provide an opinion as to whether or not FTIR would detect the functional groups on the specific antioxidant to which you refer. I mean -- I mean, you would just look at the functional groups and see if there were any distinct from the polypropylene itself.

Q. You haven't done that, have you?

A. I have not specifically gone through that particular exercise, no.

MR. THORNBURG: Okay. We can take a break.

THE VIDEOGRAPHER: We're going off the record. The time is 10:38 a.m.

* * *

(Whereupon, a recess was taken.)

* * *

THE VIDEOGRAPHER: This is beginning of disc two. We are going back on the record. The

time is 10:53 a.m.

BY MR. THORNBURG:

Q. Hi, Dr. Little, how are you?

A. Fine.

Q. Did you have a good break?

A. Yes.

Q. Did you -- did you by any chance look at any doc- -- additional documents during the break to refresh your recollection on any of the testimony that you've provided so far?

A. No.

Q. Okay. And I want you to turn to page 7 with me of your expert report, which is Exhibit 3. Are you there?

A. Yes.

Q. Okay. If you go to the second paragraph, you write, "The Marlex HGX-030-01 polypropylene resin that was used in Boston Scientific's Polyform mesh contained a primary antioxidant (Irganox 3114), a secondary antioxidant (Irgafos 168), and a stabilizer (DHT-4A)."

Did I read that correctly?

A. Yes.

Q. You write that, "The presence of" a

primary -- "of primary and secondary antioxidants further prevents oxidation and chemical degradation of the polymer in vivo."

Did I read that accurately?

A. Yes.

Q. Okay. Dr. Little, how did you determine the additive package of the Marlex HGX-030-01?

A. I'm pretty sure that it's in the documents that were provided to me in regard to the composition of the Marlex.

Q. Well, you don't cite to any documents there, do you?

A. I don't cite, in this paragraph, documents, no.

Q. Was that information, whether it was provided to you by -- you know, verbally or provided to you in one of the materials you listed in your materials reliance list or within your expert report, was that provided to you by counsel for Boston Scientific?

A. Yes.

Q. Okay. So Boston Scientific provided you with some type of information concerning the Marlex formula?

A. Yes.
Q. Okay. Including the additives package?
A. Yes.
Q. Okay. Do you know if they provided it to you verbally, or if you were provided with internal corporate documents that identified the additives package within the Marlex resin?
MS. STEELE: Object to form.
A. I remember seeing documents that included the antioxidants specifically which ones that were included in the resin.
Q. Has the additives package of the Marlex ever changed?
A. Hmm.
(Telephone beeps.)
A. Has the additives ever changed? I don't recall seeing any changes to the additive packages.
Q. Well, you have no knowledge one way or the other whether or not the additives package has changed?
MS. STEELE: Object to form.
To the best of your recollection.
A. Yeah, to the best of my recollection, no.
MR. THORNBURG: I appreciate no

counseling of the witness, please.

Q. Did you review any internal documents concerning whether or not any of the additives packages were revised or modified over time?

MS. STEELE: Object to form.

A. I don't recall that information, no.

Q. Do you know one way or the other whether there was a different formula prior to the formula that you have on page 7 which lists Irganox 3114, Irgafos 158, or DHT-4A?

A. Not that I can recall.

Q. Is that information -- would that information be important to your testimony?

A. Um, well, I mean, I think my testimony here is related to this formulation that I'm talking about regarding the Marlex HGX-030-01.

Q. Well, let me ask you this question. What quantity of Irganox 3114 and Irgafos 168 and DHT-4A are contained within Marlex HGX-030-01 currently?

A. The specific --

MS. STEELE: Object to form.

A. The specific quantities, I don't remember.

Q. Do you have -- what's the significance of the amount of these antioxidants in terms of the

stability of polypropylene?

A. Well, I mean, I didn't perform an analysis on the amounts.

Q. Do you know -- do you know how Boston Scientific determined -- strike that.

Do you know whether or not Boston Scientific ever set out to determine whether the amounts of these additives were suitable to be used in a permanent implantable medical device like its Uphold mesh and its other Marlex mesh devices?

MS. STEELE: Object to form.

A. I did not perform a specific analysis on that, no.

Q. Do you know -- do you know if Boston Scientific ever set out to determine whether or not the quantity of these stabilizers they were using in the Marlex mesh devices was an appropriate quantity to be used in permanent implantable medical mesh devices?

A. I'm sorry, your question is very similar to what I already answered before. If there's a difference, you can let me know, but I -- I don't believe that I --

Q. I didn't mean to interrupt. I apologize.

The difference --

A. That's okay.

Q. The difference is I asked you whether or not Boston Scientific ever set out to determine whether or not the quantity of its antioxidants were suitable to prevent degradation in a product that would be used in the pelvic organ tissue of humans?

MS. STEELE: Object to form.

A. Well, so what I'd say is, no, I don't remember specifically seeing that information. I'd just say that, you know, in my opinion, that's really not the point because I -- there's evidence that it's not go -- undergoing oxidation in the body. So I didn't feel like I needed that information to provide the opinions that I provided.

Q. Do you think it's incumbent upon a medical device manufacturer to determine whether or not they have chosen the right amount of antioxidants to prevent degradation in a product that's going to be implanted permanently in the pelvic tissue of women?

MS. STEELE: Object to form.

A. I mean, I'm not providing opinions on

conduct, corporate conduct.

Q. Are you going to provide any opinions regarding the industry standards?

MS. STEELE: Object to form.

A. Could you be more specific?

Q. Well, the industry standards of medical device mesh manufacturers in terms of determining the design validation of the amount of stabilizers they put in their medical devices that would be implanted in the pelvic tissue of females for life.

MS. STEELE: Object to form.

A. Yeah, I'm not providing opinions on that.

Q. Do you know if Boston Scientific ever decreased or increased the quantity of Irganox or Irgafos or DHT-4A?

MS. STEELE: Object to form.

A. Again, there may be some difference in the way you're asking the question, but I think I already answered. I don't recall seeing information related to changing the antioxidant package.

Q. If Boston Scientific changed the antioxidant package by reducing the quantity of the stabilizers, would that be important information in

rendering your opinions concerning the stability or degradability of Marlex mesh devices?

MS. STEELE: Object to form.

(Telephone beeps.)

THE WITNESS: Somebody just joined.

MS. STEELE: Or dropped off. You can answer.

A. Well, I think -- what I think is that, for instance, if -- if there were changes made, you know, were the changes, you know, relevant amounts? And I mean, I'm not providing opinions on that. So I don't recall seeing it, and I'm not providing opinions on it.

Q. So are you suggesting to the ladies and gentlemen of the jury that the amount of antioxidants used in the Marlex mesh devices is insignificant or unimportant to your opinion concerning the stability or degradability of Marlex mesh devices?

MS. STEELE: Object to form.

A. What I'm saying is, is that I think an analysis of that would have to consider the tolerance levels of the amount that -- the amounts that would be in there, the susceptibility of the

material specifically in the body to degradation, a whole bunch of things that I have not spent time doing an analysis on. So that's why I'm not providing an opinion on it.

Q. Well, if you're offering opinions concerning the stability of Marlex mesh resin, you would expect that Boston Scientific would provide to you internal studies that they would have done that would have validated exactly what you just said, whether or not the quantity of the stabilizer was sufficient to prevent degradation in these mesh products to be permanently implanted in the pelvic tissue of women; right?

MS. STEELE: Object to form.

A. No, I mean, I think what I said before, I stand by, which is that I have seen no evidence of degradation. So whether or not a change in the antioxidant package would be something that would be sufficient or not or within tolerance levels or not, I didn't perform that analysis.

Q. Doctor, you didn't even perform any analysis looking at whether or not explanted Marlex mesh devices manufactured by Boston Scientific had degraded.

MS. STEELE: Object to form.

A. I performed an analysis of the literature which includes Marlex mesh.

Q. Okay. Which literature did you analyze that specifically looked at Marlex mesh to determine whether or not the Marlex mesh had degraded?

MS. STEELE: Object to form to the extent that Marlex mesh is a specific type of mesh not manufactured by Boston Scientific.

MR. THORNBURG: Excuse me, you get to object to form. You don't get to add anything beyond that.

MS. STEELE: Okay. We can talk about hernia mesh, then.

A. I don't --

MR. THORNBURG: Hold on a second, counsel. Do you want me to call the judge and tell the judge that you've continued to interrupt and coach this witness?

MS. STEELE: You can.

MR. THORNBURG: I don't want to do that. But if you continue it, I will.

MS. STEELE: I'm just trying to make sure that the record is clear.

MR. THORNBURG: You'll have an opportunity to do that when it's your turn to direct your witness. Right now, it's my turn; okay? I'd appreciate the courtesy.

MS. STEELE: Is there a question pending?

MR. THORNBURG: There was a question pending before you interrupted.

Will the court reporter please read back the last question.

(Whereupon, reporter read pending question.)

A. I -- off the top of my head, I mean, all of these articles that I cite and have included in my materials considered list are relating to polypropylene mesh and specific kinds and there's different kinds. Specifically which ones refer to this, I can't remember off the top of my head.

BY MR. THORNBURG:

Q. Did you review the Costello publications concerning mesh degradation in Marlex products?

MS. STEELE: Object to form.

A. I reviewed the Costello -- I reviewed the Costello manuscript, but I don't believe Costello shows that the polypropylene is degrading.

Q. You don't believe -- did the authors of -- did Costello and the other authors of his peer-reviewed publications conclude that the explanted Marlex mesh had degraded?

MS. STEELE: Object to form.

A. So I -- I can pull that paper up.

Q. You don't recall off the top of your head?

COURT REPORTER: I'm sorry?

Q. You don't recall without looking at the publication; is that correct?

A. Not -- I think -- I'm pretty sure that when you look at the data in Costello that it suggests that it's not degrading.

Q. My question -- move to strike.

The question was, isn't it correct --

MS. STEELE: Oppose motion.

Q. -- that the author of that publication who actually performed the analysis of explanted polypropylene mesh devices, unlike yourself, concluded that the mesh had degraded?

MS. STEELE: Object to form. And I oppose the motion to strike.

A. (Witness reviewing.)

MR. THORNBURG: I'll go ahead and mark

as Exhibit No. 4 "Characterization of Heavyweight and Lightweight Polypropylene Prosthetic Mesh Explants From a Single Patient" by doctors and researchers Costello, Bachman, Grant, Cleveland, Loy, and Ramshaw.

(Little Deposition Exhibit 4 was marked for identification.)

Q. Do you have Exhibit No. 4 in front of you, Dr. Little?

A. I do.

Q. Have you reviewed this publication before today?

A. I have.

Q. Okay. When did you review this publication?

A. I probably looked at it again over the last couple of months, but I probably read it in more depth last year.

Q. And you understand that the University of Missouri Columbia in Columbia, Missouri is a well-respected polymer science institute and biomedical institute?

MS. STEELE: Object to form.

A. Well, I mean, I am not privy to who's calling it that. I mean, to be honest with you,

everybody says that they are well-respected institute, so.

Q. Is this a peer-reviewed publication?

A. It appears to be. It's in Surgical Innovation.

Q. Do you know -- do you know for how many decades Dr. Ramshaw has actually been personally studying explanted polypropylene mesh devices for -- to determine the stability and degradability of polypropylene mesh devices?

A. I don't know how many specific years he's been doing this. What I can say is that there's a lot -- a lot of people that have been publishing on this topic, and there's differing opinions about the conclusions that are made in here.

Q. Well, you've never published on this topic; right?

A. I have not specifically published on explanted polypropylene mesh, no.

Q. And you've never looked at a single explanted polypropylene product; right?

A. In my analysis of the literature, there are a number of different analyses that are performed on explanted tissue. I believe that I'm qualified

to look at those and provide the analysis, the results, and the conclusions that I made in my report.

Q. You've never personally -- as we've already established, you've never personally studied the stability or degradability of polypropylene mesh devices; right?

A. I've not personally done that, but I do not feel like I have needed to personally do it to provide the opinions in my report.

Q. Okay. And do you know who Dr. Ramshaw is? Have you ever heard of his name before?

A. I have not met him, no.

Q. Did you ever listen to him lecture?

A. No, I have not.

Q. Have you ever attended any lectures on the degradability or the stability of polypropylene mesh devices?

A. I probably have seen presentations that were made at the Society For Biomaterials on the topic. I'll say that there's, to be quite honest, compared to everything else, very small numbers of talks that are given on this particular topic.

Q. Probably -- saying you probably have doesn't

really cut it for me, Doctor. Do you specifically remember or recall ever personally attending any presentation concerning the degradability or the stability of polypropylene medical mesh devices; yes or no?

A. Like I told you, I said that I remember seeing some things on polypropylene and would have been in implants and also meshes, so I have attended lectures. But like I said, there's not very many of them. It's not a topic that is a huge debate in the scientific field.

Q. Who presented on the topic of polypropylene mesh devices that you're claiming to have attended?

MS. STEELE: Object to form.

A. Again, I'm saying I remember seeing some talks. I don't remember specifically who was giving that talk.

Q. How long ago did you attend that presentation?

A. It would have been in the last ten years.

Q. Where -- where was the presentation given?

A. Oh, it was most likely at a Society for Biomaterials meeting.

Q. Did you sign in that day?

A. You don't sign in at the Society for Biomaterials.

Q. Okay. In any case, you don't know who Dr. Ramshaw is?

A. No.

Q. Okay. Now, if you turn to page 169, or page 2 of Exhibit 4 -- are you there?

A. Yes.

Q. The top of the left-hand page, the first full paragraph that reads, "Surgeons have also historically considered polypropylene to behave as an inert material while in vivo. However, polypropylene is susceptible to oxidation, resulting from exposure to strong oxidants such as hydrogen peroxide and hypochlorous acid. These by-products of the inflammatory response may degrade and embrittle the material, causing it to become" brittle (sic).

Did I read that correctly?

MS. STEELE: Object to form.

A. You read it -- you read it correctly from this page, yes.

Q. You would disagree with -- with this scientist, wouldn't you?

A. Well, there's a lot of people that disagree with this scientist, and I think there's a lot of evidence that shows that it isn't. It's referring to articles that go back that provide a hypothesis on this particular idea, but this idea has been rutted -- rebutted even by the individuals who published these articles stated that, that they can't conclude that this is specifically what's going on.

MR. THORNBURG: Move to strike, nonresponsive.

MS. STEELE: Oppose.

Q. My question was very simple. You disagree with these researchers' opinion or comment that surgeons have "historically considered polypropylene to behave as an inert material while in vivo; however, polypropylene is susceptible to oxidation, resulting from exposure to strong oxidants such as hydrogen peroxide and hypochlorous acid"; right? You would disagree with that?

A. Yes.

Q. And you would disagree with the statement here that, "These by-products of the inflammatory response may degrade and embrittle the material,

causing it to become rigid." You would disagree with that?

A. Yes, no one's shown that. It's completely speculation.

MR. THORNBURG: Move to strike.

Q. It's yes or no, Doctor.

MS. STEELE: Oppose.

Q. Whether you agree with something or disagree with it, that's a yes or no question; okay?

Now, the sentence goes on to say, "Materials used for other types of medical implants (polyethylene in orthopedics and polyurethane in pacemaker leads) have also demonstrated degradation secondary to oxidation."

Do you agree or disagree with that?

A. Well, I mean, I'll say that I haven't spent as much time looking into polyethylene, for instance, as I have polypropylene.

Q. Well -- but the only time you've spent researching this issue specifically was when you got involved in this litigation.

A. Well, I mean, I would say that's not right. I mean, I definitely was aware of what was going on in this general area before this point.

Q. Okay. And if you -- look at the case description, do you see that?
A. Yes.
Q. Okay. And this describes a -- a female patient who underwent hernia surgery; correct?
A. Yes.
Q. And do you know what products she had implanted?
A. Looks like she had a PTFE mesh that was implanted in 1997. (Witness reviewing.)
Q. She also had a Kugel implanted?
A. October 2001, yes.
Q. Okay. And do you have any background in Kugel mesh?
A. Well, I know that it's a PTFE mesh, polytetrafluoroethylene.
Q. Is it a -- is it a -- is there any polypropylene in it?
A. I'm not aware of there being polypropylene in it.
Q. Is it a composite?
A. It is. I don't remember the specifics of the composite.
Q. Okay. Do you recall what the results were

from this study?

A. Yeah, I mean, the results section shows the explanted -- showed the explanted Kugel composite mesh. And it is polypropylene composite and PTFE. And there's SEMs, DSCs. There's a TGA analysis. And the following pages.

Q. Do you know what resin Bard used in its Kugel composites, which polypropylene resin?

A. Off the top of my head, no, I don't remember.

Q. Do you know if it was Marlex?

MS. STEELE: Object to form.

A. I mean, if it's in the manuscript, I can look here. I don't remember off top of my head.

Q. Would you consider whether or not it was Marlex?

Did you -- did you ask Boston Scientific if Bard also used Marlex resin?

MS. STEELE: Object to form.

A. I mean, I don't remember if I had that conversation. Again, this was sort of in the context generally of polypropylene.

Q. Okay. And these scientists performed scanning electron microscopy; right?

A. Yes.
Q. Differential scanning calorimetry; right?
A. They did, yes.
Q. Thermogravimetric analysis, TGA; correct?
A. Yes.
Q. Histology; right?
A. Yes.
Q. And those were all studies that you or -- or techniques that you, I believe, testified that you could do but were not asked to -- to do on any explanted Boston Scientific Marlex products; correct?
MS. STEELE: Object to form.
A. Right. So I was not asked to do that. You know, if there was -- if there were mesh available, then I think that it would be helpful to perform the analysis. But again, with respect to the report -- the conclusions that I -- I come up with in my report, that's based on the literature.
MR. THORNBURG: Move to strike everything after, I was not asked to perform that analysis.
MS. STEELE: Opposed.
Q. If you look at the conclusion section of

this article, the authors conclude that overall, "The results support our hypothesis that in vivo oxidation plays a role in the degradation of polypropylene hernia mesh materials and that there may be a difference in the degree of oxidation between a heavyweight material and a lightweight material because of a reduced inflammatory response."

Did I read that correctly?

A. Yes, you did.

Q. Do you agree or disagree with that statement?

A. I disagree with that, and I can tell you why specifically.

Q. What's the basis for your disagreement?

A. Well, so first of all, these meshes weren't cleaned. They were only cleaned for two hours. And they were placed in formalin. So it's clear from the literature --

Q. So, they weren't -- hold on -- hold on one second.

MS. STEELE: He was still finishing his answer.

Q. But you said they weren't cleaned but they

were cleaned; correct?

A. Should I --

MS. STEELE: You can answer.

A. -- finish my answer?

MS. STEELE: Finish your answer.

Q. They were cleaned; correct?

A. Well, they were -- they were -- okay. So it depends on what you mean by cleaned. What happened was they were placed in, essentially, bleach for two hours, okay, which --

Q. What type of material -- what type of reagent were they placed in to remove the tissue?

A. Sodium hypochlorite solution, 6 to 14 percent active chlorine, two hours, 37 degrees, and then rinsed.

Q. Okay. So you've never performed a -- you've never attempted to clean tissue off of any polypropylene explanted device; correct?

A. Again, specifically, I have not analyzed polypropylene explants. But I can tell you that it's clear from the literature that this is not enough to clean it; and that's why previously, when I was answering the question, when you said cleaned, it's clearly not cleaned.

Q. You didn't -- did you compare the protocol used by these researchers to the protocol established by the ASTM?

MS. STEELE: Object to form.

A. I recall in the ASTM that there's more to be done to clean the explants. The specifics, I can't recall. But it's clear from this paper, that it's not cleaned.

Q. Can overexposure to sodium hypochlorite lead to oxidation of polypropylene?

A. Um, I think that studies have been done, off the top of my head, to show that exposure to sodium hypochlorite did not result in oxidative degradation of polypropylene. But what I can tell you is, is that if all you do is do this level of attempt at cleaning and it doesn't clean it, then your results that are based on, you know, for instance, SEM analysis where it says that, you know, you can see a film on the top and it's cracked so therefore it's -- proves that it's degraded, that's a -- that's a faulty conclusion.

Q. Is your opinion that it was not cleaned well enough based on your review of the publications by Dr. Thames and Dr. de Tayrac?

A. That's one of the papers. It's one of the more recent ones. But there are other papers in the past as well where you can --

Q. Which papers? Which papers?

A. Well, you can see, for instance, in Dr. Mays' paper that that level of cleaning doesn't remove the tissue. It's very clear there's tissue, and I'm pretty sure that he even admits that it's not cleaned off, that there's tissue there.

Q. That's your opinion; right?

COURT REPORTER: I'm sorry?

MS. STEELE: He was still finishing.

Q. That's your opinion; correct?

A. I --

Q. Correct, Doctor?

A. Do you want me to keep going, or do you --

Q. Well, let me ask you --

A. -- did you ask a new question?

Q. -- is it fair to say that the -- the -- the focus of your opinion that you rely on comes from Dr. Thames and Dr. de Tayrac?

MS. STEELE: Object to form; asked and answered.

A. So I was answering the question before. I'm

lost in the -- I'm trying to answer your questions, and -- and you're interrupting me, so I don't know what question we're on.

Q. So your -- your opinion that these authors and authors like Dr. Ramshaw and others who have concluded that explanted polypropylene mesh material degrades in vivo is based primarily on your reliance on the publication by Dr. Thames and Dr. de Tayrac; correct?

MS. STEELE: Object to form; asked and answered.

A. I think -- what I would say is that those two manuscripts are evidence of what I'm saying, but there are a number of other manuscripts that show that the type of cleaning that's performed is not removing biological tissue. And I gave an example, one of which was a manuscript where the corresponding author was Dr. Mays; I believe the first author was -- last name was Imel.

Q. Dr. Mays who has concluded that explanted mesh devices degrade; correct?

A. Well, so, for instance, he's concluding that they degrade because he can see cracks on the surface in the same way that this is concluding

that there's cracks on the surface, but you can't use that as evidence if the material is not cleaned off.

Q. Okay. So the basis for your -- the primary basis for your opinion sounds to me like Dr. Thames, Dr. De Tayrac, and some of the work that Dr. Mays has done in this litigation; is that correct?

A. And others.

Q. And you don't -- sitting here today, you can't name any others?

A. I'd be --

MS. STEELE: Object to form.

A. I'd be happy to go through and look at these to see all of the ones that suggest that it's not cleaned off. I mean, you go back to the earliest papers and the authors say that you can't conclude that it's oxidative degradation because it's possible that it's still biological material on there.

Q. Okay. Well, let's look at Dr. Thames' publication really quick. We'll mark that as Exhibit No. 5.

(Little Deposition Exhibit 5 was marked

for identification.)

Q. Are you there?

A. I am.

Q. Okay. And we're looking at the publication by Dr. Thames, Joshua White, and Kevin Ong; correct?

A. Yes.

Q. Okay. And if you look at each -- each one of their names has a footnote. Do you see that?

A. Yes.

Q. Okay. And are you aware that -- from reviewing this publication that Mr. White and Mr. Ong work for a company called Exponent?

A. Yes.

Q. Okay. And are you aware that Exponent has been retained by the mesh manufacturing defendants including Boston Scientific --

MS. STEELE: Object to form.

Q. -- concerning the issue of mesh degradation?

MS. STEELE: Object to form. We have not -- assumes facts not in evidence.

Q. Well, are you aware that Exponent has been retained by Bard and Ethicon, at least?

MS. STEELE: Object to form.

A. I'm pretty sure that this says that the work done by -- there was work done by White and Ong for Ethicon, yes.

Q. Do you know how many millions of dollars Exponent has been paid to serve as experts by Ethicon, Bard, and others in the context of this mesh litigation?

MS. STEELE: Object to form.

A. I do not, but if the implication is that they've been paid to forge this data, it would be ridiculous. When you look at this paper, it's very clear. Everything is shown. It's described in detail. The results are very clear.

Q. Do you agree that money can impact the biases of witnesses?

MS. STEELE: Object to form.

A. I think that it's possible that money can impact biases of witnesses. In this case, you're talking about Shelby Thames, who, you know, I -- I guess I can't imagine, you know, that name and then looking at this paper, where, you know, basically everything is shown. It looks like everything's very clearly shown here. There's nothing hidden.

MR. THORNBURG: Move to strike.

Q. We're going -- we're going to talk about the -- the details --

MS. STEELE: Opposed.

Q. -- of the study, but you aren't aware that Exponent has been paid millions of dollars --

MS. STEELE: Object to form.

Q. -- by the manufacturers who are defendants who are defending claims by plaintiffs concerning injuries they suffered as a result of polypropylene mesh devices? You aren't aware of how many millions of dollars they've been paid; correct?

MS. STEELE: Object to form.

A. I am not aware of the details of their payment.

Q. Do you know or were you aware that Dr. Shelby Thames is also a paid expert in the Ethicon and Johnson & Johnson polypropylene mesh litigation?

MS. STEELE: Object to form.

A. I'm not aware of the details of that, no.

Q. Do you know how many millions of dollars Dr. Shelby Thames has been paid concerning his work in the mesh litigation?

MS. STEELE: Object to form.

A. I'm not.

Q. But all of these authors are paid experts in the Ethicon litigation; correct?

A. Yeah, and I think that most of the authors publishing on this topic today are paid by either plaintiffs or defendants.

Q. Well, what about Dr. Ramshaw; is he paid?

A. I don't know the details of -- of specifically who's getting paid what. No, I don't know.

Q. Okay. Assume with me that Dr. Ramshaw is not a paid expert in this litigation. Okay?

A. Okay.

Q. And he concluded -- he concluded, which you had disagreed with, but he concluded that polypropylene mesh degrades; correct?

MS. STEELE: Object to form.

A. And we talked --

Q. And --

MS. STEELE: He was answering.

Q. So let's look at the cleaning protocol that was used by Dr. Shelby Thames. On page 288 of Exhibit 5.

MS. STEELE: You may need to look at the

one she gave you.

A. (Witness reviewing.) Okay.

Q. Okay. And Dr. Thames lays out a 23-step cleaning process; correct?

A. Yes.

Q. Where he exposed the explanted mesh materials to hours and hours of sodium hypochlorite; right?

A. Yes.

Q. Have you ever sodium hypochlorite to remove tissue from any explanted device?

A. Yes.

Q. Okay. Which device?

A. It was -- I believe that we just used it to clean off some implants that we had that were made of -- the materials we used was some polyester-based materials.

Q. Okay. And did you publish that in a peer-reviewed publication?

A. I don't recall.

Q. And how did you validate your -- your cleaning protocol?

A. I'm not understanding, how did you validate it.

Q. Did you validate your cleaning protocol?
A. No, we didn't -- I'm just saying that we used it to try to clean off some things. We didn't go through validation stages.
Q. How many hours of -- how many hours did you expose the -- that device to after it was explanted? How many hours did you expose it to sodium hypochlorite?
A. I don't remember.
Q. Was it an hour or less?
A. I don't remember.
Q. Can you give me a fair estimation?
A. I -- I don't remember.
Q. How many hours did Dr. Thames expose the explanted Prolene mesh devices to?
A. In the first -- in the first cleaning sequence, it was five minutes to six and a half hours depending on the bulk tissue. Cleaning sequence two, it was one and a half to two hours. Three was four to six hours. And then cleaning sequence five included a four to twenty hour exposure.
Q. So up to thirty-four and a half hours?
A. Yeah, approximately, yes.

Q. Okay. And he also shook the explanted devices in sonication and ultrasonication machines for several hours; correct?

A. Yes.

Q. And he also exposed it, these explanted devices, to -- to Proteinase K; correct?

A. Yes.

Q. And do you know when he actually performed any FTIR analysis of these explanted devices, what step?

A. It was in the materials characterization step after cleaning, in the blue.

Q. Which step was that?

A. It would have been after all of the steps in the blue box.

Q. Is it your understanding that he used FTIR at each one of those material characterization phases?

A. Yes, if you go to Figure 6, it says -- there's the FTIR of the progressive cleaning steps.

Q. Okay. And -- and so the blue one would have been the first step and -- and then this is just layover of each one of the steps; correct?

A. Yes.

Q. And the blue -- the first blue step would have been the very first FTIR that he would have performed; correct?

A. Yeah, before cleaning.

Q. Which shows an FTIR spectrum at 165167, and 158372, correct, and a number of other spectrums, but --

A. Yep.

Q. -- those are spectrums closest to a spectrum where you could see oxidation?

MS. STEELE: Object to form.

A. Well, what you -- what you would see is you would see peaks, but if there's biological material there, you wouldn't be able to see oxidation.

Q. Doctor, where would you see a peak at on an explanted polypropylene mesh if it was oxidized?

A. Well --

MS. STEELE: Object to form.

A. Differentially from the regular polypropylene, you could see that were ultimately results of the disproportionation reaction that is hypothesized to occur on these kind of implants in vivo, and it would be in the regions that are shown here with the green; but in those two regions, you

would also see similar peaks for amide bonds.
Q. Well, you'd see double amides; right?
A. I'm sorry?
Q. You'd see a double amide if it was protein; right?
A. Well, I think -- I think that you would see peaks there. What exactly you would see I think would depend on all kinds of things including formaldehyde fixation and -- I mean, I'm not going to comment on specifically what you would see.
Q. Well, do you know what you would see if you had protein?
A. Yeah, I mean, you would see -- you would see peaks that would --
Q. A double -- a double amide; right?
MS. STEELE: Please don't interrupt him.
Dr. Little, you can finish your answer.
A. You would see stretching and bending peaks -- peaks associated with amide bonds which would be your carbon double-bond oxygen, which is your ketone group, and you could see stretching from single bonds that would be over to the left.
Q. Where would you see the double amide peak?
A. The double amide peak, what are you

referring to? Double amide peak?

Q. Yep, are you familiar with double amide?

A. Double amide. I'm not -- I'm not remembering what you're talking about here with double amide. Could you please define?

Q. Can you define it? You've never heard of it before? You're not aware of it?

A. The specific term that you're using, "double amide," I'm not -- no, I'm not remembering. If you could -- if you could tell me what you mean by that.

Q. Well, let me ask you this question. If you had oxidized polypropylene, you would see a -- an oxidization peak on the FTIR spectrum at somewhere between 1800 and 1650, approximately; correct?

A. I think you would see that, yes.

Q. And have you ever intentionally oxidized polypropylene before?

A. I've not intentionally oxidized it, no.

Q. Have you ever looked at any studies that intentionally oxidized polypropylene to determine where the peak would be located in a degraded -- intentionally degraded polypropylene mesh?

A. I think so, yes, I remember studies with

that.

Q. Okay. And would 1740, give or take a few reciprocal centimeters, sound about accurate?

A. In that range I think that sounds like that makes sense. There can be shifts for various reasons, but yes.

Q. That's why I said give or take a few reciprocal centimeters; right?

A. Well, I don't know if I -- I would say give or take a few reciprocal centimeters; I would need to look into that, but I know shifting can occur.

Q. Have you looked into that?

A. Looked into specifically all of the circumstances and -- no, I have not. But I just know that it's -- it can be in that area and then it can -- it can shift depending on the circumstances.

Q. Okay. And if we look at the top figure on page 291 of Exhibit 5, have you ever -- have you been trained in looking for shoulder peaks?

A. Have I been --

Q. Do you know what I mean by shoulder peaks?

A. Well, if you're -- if you're referring to something that would overlap that would look like a

shoulder, I think I know what you mean.

Q. Okay. What do you think I mean?

A. That's what I just described to you. But --

Q. You could have -- you could have one -- you could have two peaks that are -- one that you can only see the shoulder and the other where you can see a higher peak which is identifying chemical differences?

MS. STEELE: Object to form.

A. Um, so I think I know what you mean. I'm not -- I'd have to look into this a little bit more to -- to determine what could be responsible for it. I know that it can represent multiple peaks.

Q. It could represent two different bidens (phonetic); correct?

A. Again, I'd want to look into this, but I think it can, yes.

Q. Okay. And on -- if you look at the top figure, you can see there's a peak at 1651?

A. Okay.

Q. And do you see there's a shoulder on that broad peak at between 1800 and 1740?

MS. STEELE: Object to form.

A. I think I see what you're seeing; I'm not

sure I would call it that.

Q. What would you call it?

A. I don't know. I mean, whether or not that is a signal that could be attributed to any particular thing, I'm -- I'm not sure they say, nor would I be able to say.

Q. Well, you know, in the Wood article, Dr. Wood and her colleagues who actually personally analyze explanted polypropylene, had determined that in their conclusion polypropylene had degraded based on a peak at about 1740 reciprocal centimeters; correct?

A. Let me find that paper.

THE WITNESS: Do I have it here, Andrea?

MS. STEELE: Yes. It's Tab 12.

THE WITNESS: Okay.

MR. THORNBURG: We'll go ahead and mark Wood as Exhibit 5 -- I'm sorry, 6.

(Little Deposition Exhibit 6 was marked for identification.)

THE WITNESS: Thanks.

MS. Steele: Yep.

Q. Are you there?

A. I am.

Q. Okay. And have you -- are you familiar with the Wood article?

A. I am.

Q. And you understand in -- that the researchers in this article had determined that the poly- -- explanted polypropylene had degraded based on their FTIR analysis?

MS. STEELE: Object to form.

A. Well, I think they -- they said that it -- that's one of their conclusions, but they make conclusions about the other two materials as well, that are similar.

Q. Well, that's fine. But their conclusions about polypropylene was that it degraded; correct?

A. Well, I think their conclusion is that all three of them do; but, you know, for instance, these other two polymers don't even have the bond that we're talking about breaking, so.

Q. Okay. Do you want to talk about the bonds of the other two polymers? Because we can if you want to. Or do you want to focus on the polypropylene here for a minute?

MS. STEELE: Object to form.

A. Are you asking -- is there a question?

Q. Yeah. Let's -- why don't we try to focus on my question; okay? The authors of the Wood article determined that the polypropylene explant -- explants had degraded in vivo; correct?

MS. STEELE: Object to form.

A. (Witness reviewing.) Well, they conclude --

Q. Let me -- let me do you a favor. If you to turn page 1120.

A. Yeah, I'm there. That's actually what I was going to be reading from here.

Q. Okay. And this is under the section they title Polypropylene; correct?

A. Yes.

Q. Okay. And these authors summarize their findings; correct?

A. Yes.

Q. And they write that both the scanning electron microscopy and ATF -- ATR-FTIR provide characterization of the surface morphology and surface chemistry, respectively, but it is also necessary to determine if the bulk properties of the polypropylene material also changes. Figure 6 displayed MS -- I'm sorry -- MDSC data which showed a significant difference in delta H -- do you know

what delta H means?

A. I do.

Q. What does delta H mean?

A. It is the -- well, it's a enthalpy. It's a change in enthalpy.

Q. It's the -- is it the heat of fusion or the change in enthalpy?

A. Here the delta H -- the difference is delta H and melting point -- it's the heat -- it's the heat of enthalpy.

Q. Right. And they're -- and they compared the heat of enthalpy to what, Doctor?

A. It's enthalpy.

Q. The heat of enthalpy to what, Doctor?

A. The -- the graph shows the molar heat of enthalpy per -- for the individual groups.

Q. Okay. So they were performing some thermal analysis; is that accurate?

A. Yes.

Q. Okay. And they determined that the explanted samples of the polypropylene displayed a lower heat of fusion and lower melt temperature; right?

A. Well, they -- they determined that what they

analyzed showed a change, but that included --

Q. Right.

A. -- the polypropylene and any of the other biological material that would have been on or in it.

Q. Well, it was indicative of oxidatively degraded polypropylene, wasn't it?

MS. STEELE: Object to form.

A. No.

Q. Pardon me?

A. No.

Q. Based on what?

A. Well, if you have other material in there, especially if the polymer is, for instance, plasticized, it's going to demonstrate different properties using thermal testing.

Q. What's that opinion based on, Doctor? Your review of Dr. -- that's based on your review of Dr. Thames' report; right?

MS. STEELE: Object to form.

A. No. It's based on understanding that if you have a plasticizer in a material, it's going to change the thermal properties.

Q. How so?

A. Well, um, the thermal properties are based on -- I mean, you're basically heating the material up. So everything's wiggling around, and then it wiggles around more. And then when it goes through a change, for instance, the amount of heat that causes it to go through that change can be examined. But when you have something that, for instance --

Q. Well --

A. -- is between the chains leading to chain movement or more chain movement, then it will change the rate or -- the rate of change or the amount of heat required in order to observe a thermal event, for instance.

Q. Well, do you know if it changes it in a way that would make it more difficult -- in other words, you'd have to have more heat applied to the explant to remove the material -- to melt the material or less?

A. Um, well, I mean, you've -- you now have other material on there, too, so I guess I'm -- I'm not sure exactly -- I mean, it just becomes more complicated whenever you have biological material in there. The example that I just gave you, which

is that you would have a plasticizer in it, then that means that there would be less heat, but that's for that specific example, to go through a transition.

Q. Would -- it's your opinion that a plasticizer -- and by plasticizer, are you suggesting to the ladies and gentlemen of the jury that when explanted polypropylene material is placed into formalin it becomes a -- there's some sort of formaldehyde-protein bond that occurs?

A. Well, so now we're talking about, I think, something different. But yes, if you have biological material that's on the fiber, for instance, protein specifically, and you add formalin, then it can form crosslinks in a protein coat.

Q. Would that -- would that cause the polymer to be more difficult to melt or easier to melt?

MS. STEELE: Object to form.

A. Well, like I said, I think it's sort of complicated because you could potentially have fatty acids that would be there, too. And the rate at which each of these would impact the final results, I'm not sure.

I think that what I'm trying to say is that what's really important is that you -- you clean them properly before you do this. I think these results can be --

Q. It's also important --

MS. STEELE: He's still speaking.

Q. I apologize. But if you're reading the data and you're drawing conclusions from the data, it would be important for you to know or to offer an opinion as to -- and back that opinion up as to why you think their conclusion that the DSC findings demonstrated or were indicative of oxidatively degraded polypropylene was incorrect and then back that up.

A. Well, I was -- I was --

MS. STEELE: Object to form, and it mischaracterizes the article.

A. Yeah, I mean, I was answering the question and you interrupted me.

Q. You said it was complicated. It's a very complicated thing. Well, do you know whether or not the heat of enthalpathy -- enthalpy will go down or will go up if this material -- if this explant was not properly cleaned and was put in

formaldehyde?

MS. STEELE: Object to form.

A. And so what I was trying to say before is that you have multiple species that could be exhibiting a number of different effects here. So what I think is that what's really important is that you clean it and you show that it's cleaned. So what you're doing is your analyzing just the polypropylene before you come to your determination.

Q. Okay. And if you -- if you turn to page 1114 of Exhibit 6, you're not suggesting that Dr. Wood, Dr. Cozad, Dr. Grant, Dr. Ostdiek, Bachman, or Grant didn't clean this explanted material, are you?

A. I'm suggesting that the final result was that it was not cleaned; they place it in 10 percent formalin solution and then also used sodium hypochlorite but that that did not clean it.

Q. Okay. But they -- do you know what their experience is on removing tissue from explanted materials?

MS. STEELE: Object to form.

A. Well, I can say here that it says "remove

residual tissue," but what, you know, they're not talking about here is the amount of biological material that would be directly on the surface of the -- the mesh. And I'm also referring to a number of different articles that literally show tissue still there; and that includes Dr. Mays' article, and it also includes Dr. Thames' article, amongst others.

Q. We're going to get -- we're going to get there; okay? So let me ask you this question. If there was material still there, the FTIR would show a peak -- strike that.

If there was biological material still present in this explant that Dr. Wood and her co-authors looked at, there would be a biological finding on their spectrum; right?

MS. STEELE: Object to form.

A. Well, yeah, I mean, it's the same peaks we're sort of talking about. You would see these ketone groups.

Q. Yeah, like at 1650; right?

A. In that area, yeah. But --

Q. Okay. And --

A. -- it could be definitely the peak that

they're seeing here in Figure 3.

Q. If you -- if you turn to 1118?

A. Okay.

Q. So these authors, not only did they do DSC and determine that it was -- their DSC findings were indicative of degraded polypropylene, but they also did FTIR; correct?

A. Yeah, but you -- there's some things in what you just said that have a bunch of assumptions in it that I don't agree with.

Q. Well, you may not agree with them, but that was the conclusions of these -- these authors who actually looked at explanted polypropylene; correct?

MS. STEELE: Object to form.

A. Well, so -- okay. There's a couple of issues here. So first of all, when you say degraded, we're talking about a technique that can look, you know, what, less than a -- the size of a human cell, down into this fiber. So at best, you are saying that you're seeing these C double bond O peaks on the surface, which is -- does not in any way indicate that the material is degraded; right?

So at best you're seeing a signal on the

surface of the fiber, and analysis of the degradation of the material would require you to perform a whole bunch of different things; cross-sectioning, it would require you to do things like mechanical analysis, all this. So I just want to make sure the record's clear --

Q. Well --

A. -- that this is not showing degraded -- biomaterial's perspective degraded polypropylene. At best it would show signals on the surface.

Q. Well, hold on a second. DSC in this particular publication -- DSC is a bulk analysis; right?

A. Yeah, but we talk -- we just talked about that.

Q. Well -- but hold on. We're going to talk about some of the other data, but DSC is a bulk analysis; correct?

A. Yes.

Q. And in that bulk analysis that these researchers performed, they determined that the polymer fiber, the polypropylene polymer fibers, had undergone oxidative degradation to such a degree that there was actually a drop in the

molecular weight.

MS. STEELE: Object to form.

Q. That was their conclusion; right?

Because you -- you understand, don't you, Doctor, that if there's a drop in the DSC then you can correlate that drop to -- you actually correlate that drop to a drop in the molecular weight; correct?

A. In a sample that is properly cleaned and that's all you're looking at, you could correlate that to a number of things including, potentially, a drop in molecular weight.

Q. And that's what these authors are -- are attempting to show; correct?

MS. STEELE: Object to form.

A. That's what they're speculating based on the data that they have.

Q. Now, you testified a moment ago when we looked at Dr. Thames' publication, the scientist who's a paid expert and has been paid, his group, his co-authors have been paid millions of dollars by defendants in this litigation -- but you opined that their FTIR of the first explanted material showed a peak at 1650 which was indicative of

biological material; correct?

MS. STEELE: Object to form; comments by counsel.

A. Could you repeat the question? I'm -- I'm losing you here.

Q. Well, when we looked at Dr. Thames' publication and there was a peak at 1650, you suggested that peak was biological in nature; correct?

A. Yes.

Q. And I'm not disputing it because that was before he'd really cleaned the material; right?

MS. STEELE: Object to form.

A. This sample was before cleaning, that you're referring to, I believe.

Q. Okay. So now if we look at -- back to Dr. Wood's article on 1118, we look at the spectrum for -- sorry, on page 1117 -- okay, are you there?

A. Yes.

Q. Okay. There's a peak at 1740 reciprocal centimeters; this is of the -- their cleaned polypropylene explant; right?

A. I don't agree that it's cleaned. It has gone through a procedure to remove some residual

tissue.

Q. There's -- there's a peak at 1740; correct?

A. There is a peak at 1740 in the explanted, yes.

Q. And you've testified earlier that a -- if you intentionally oxidized polypropylene that you would see a peak at about 1740, give or take a few reciprocal centimeters; correct?

A. No.

MS. STEELE: Object to form.

Q. That wasn't your testimony?

A. No.

Q. Okay. The record will speak for itself.

If you look at page 1117, we have the explanted polypropylene, and there's a peak at 1740; right?

A. Yes.

Q. And there's -- there is not a large, broad peak at 1650, is there?

A. Um, there's not a peak indicated here, no, at 16 -- you're saying what was the -- the reciprocal centimeters?

Q. 1650 reciprocal centimeters.

A. I -- I guess what I would say is that I

think that your 1740 here is biological material.
Q. Based on what?
A. Based on --
Q. Based --
A. -- how you can still see that there's biological material on the fibers.
Q. Have you gone to the Aldrich Library?
A. The Aldrich Library, no.
Q. You haven't gone to the Aldrich Library to see what protein or biological material, what the spectrum would be -- where the spectrum would be found?
A. Um, I mean, I generally understand where the -- where you're going to see signals here. It's actually, you know, indicated in the articles that we just looked at.
Q. Okay. And they said that the spectrum would be found at 1650 if it was biological in nature?
MS. STEELE: Object to form.
A. No, there's a -- there's a number of peaks you'd see. What I'm -- what I don't think it's -- you can comment on is where exactly you're going to see this here, depending on how it's run, depending on what is going on in the sample. What I think is

that in the -- in the Wood article what you're seeing there is biological material for multiple reasons, not the least of which that you can literally see it on the fibers.

Q. Doctor, you didn't go -- you didn't make any attempt to go to the Aldrich Library to see where biological material would show up on a -- on a spectrum, FTIR spectrum?

MS. STEELE: Object to form.

A. I didn't specifically go to the Aldrich Library, that specific source; but from my understanding and education, you would see biological signal where you're showing me this is happening in -- on page 117 of Wood.

Q. Have you gone to any spectrum -- FTIR spectrum library to determine where on an FTIR spectrum biological material would appear?

A. I may have in the past; it's my understanding just from my education and experience.

Q. On your education and experience?

A. Yeah, and I mean, the work of a number of others here in this area that are concluding the same thing as me.

Q. Have you ever found in any of the library spectrums that you've looked at that protein or biological material would give you an FTIR spectrum at 1740?

MS. STEELE: Object to form.

A. I mean, I could look at the charts. There's a number of different signals that it could give you in those range. You have bending; you have stretching. I mean, I'm not commenting specifically on where you'd get it or whether you're going to see it only in one place.

Q. Isn't that the purpose of FTIR?

A. There's limitations to what you conclude with FTIR. So what I don't think is what you're implying is correct which is that you'd be able to look at the difference here between 1740 and 1655 and tell the difference between the amide bond -- they're a range. So whenever you look at the charts that are published for this, when you see it, there's a range that's given.

Q. But you understand based on your knowledge, training, and experience that the amide -- amide bonds would appear somewhere on a spectrum of 1750 to 1500.

A. There's a range -- no. So what I said, there's a range and there's also multiple bonds.

Q. But there's -- you can't point to one source of information as you sit here today that would suggest that an amide bond one or two, would -- would appear in the 1740 reciprocal centimeter range; right?

MS. STEELE: Object to form.

A. No. What I'm saying is, is that when I have looked in the past to see, you know, where you can find some of these peaks, there's a range that's given. Whether it's specifically the range that you're talking about and giving me right now, I would have to look into that to see what that is. There's almost always a range that's given, and those ranges can shift depending on the circumstances.

So I do not think that you can specifically call out that there's a difference between 1740 and 1650 and therefore the two things are different. That's my opinion.

Q. You don't -- your opinion is that the Aldrich Library, for example, if it showed that an amide bond would be somewhere below 1700 reciprocal

centimeters, you would disagree with them? You'd disagree with the Aldrich Library?

MS. STEELE: Object to form.

A. Well, so what I would say is, again, that it's going to depend on your circumstance and your sample that you're testing. There's multiple peaks that we're seeing -- that you can potentially see in these samples; those have each a range. So what I'm saying is it's my opinion that you can't just pick one that was done at 1740, disparately in another example and experiment pick one that's at 1650, and say that those two things are definitely distinctly different.

Q. Have you gone to the Aldrich Library to look for potentially oxidized isotactic polypropylene to determine where the oxidation peak would appear on an FTIR spectrum?

MS. STEELE: Object to form.

A. I have not specifically gone to the Aldrich Library.

Q. Isn't that the purpose of the Aldrich Library? To help scientists or people who are going to testify in trial to help them look at the Library to determine that they're properly

characterizing these chemicals --

MS. STEELE: Object to form.

Q. -- or these chemical findings?

A. Well, I mean, any of these databases can help you to properly identify them; but I don't believe that it's the purpose of the Library to say that you're going to be able to look at a spectrum like you're looking at in Wood, look at a spectrum like you are in Thames and say that those two are distinctly different chemical entities done in different experiments. No, I don't believe that.

Q. You think -- you think -- your opinion is that the 1740 that we see, the very high, strong 1740 peak that we see in the Wood article, that you cannot offer an opinion one way or the other if there's any difference between the 1650 peak that we see in Dr. Thames' work?

A. Like I said, you're looking at --

MS. STEELE: Object to form.

A. -- multiple bonds here. So could -- could the predominance of the peak in Thames here be an amide double bond and the predominance of the peak that you're seeing here in Wood be a fatty acid carbon-oxygen double bond? I don't know. I know

there's lots of bonds.

What I would say is this, which as I said before, that the most important thing is that you properly clean it, you confirm that, and then you could perform this analysis and make conclusions -- which Wood clearly didn't do.

Q. So you're critical of Dr. Wood's conclusions, but you didn't take the time out of your day while working on this litigation to go and look at the Aldrich Library or some other spectrum library to determine whether or not, for example, cholesterol -- cholesterides, fatty acids, or whatever you just said, would have a -- an FTIR peak at 1740 --

MS. STEELE: Object to form.

Q. -- right?

A. No.

Q. You didn't -- you didn't do that.

A. No, I did. I -- I looked to see what the ranges are and confirmed them to make sure that my understanding was correct; but what I recall, and this is typical, is that you see ranges of these things. In addition to the ranges, they can shift depending on the circumstance. In addition to

that, you may have different bonds. So an amide double bond under one circumstance could give you -- could give you a difference in signal from a carbon double bond oxygen on a fatty acid that's not in an amide configuration.

So to be honest with you, I don't understand the need to go to this particular database you're talking about to make the confirmation. I feel like I could do that without looking into that particular database.

Q. Okay. But you didn't do that in preparation for your opinions in this litigation; correct?

MS. STEELE: Object to form.

A. I didn't look at that particular database, but I did check to see when I looked to see whether it was in the ranges that I remember, and there's nothing that would indicate to me that I needed to then somehow go to the -- to the Aldrich database.

MR. THORNBURG: I'm going to go ahead and mark really quick as Exhibit No. 7 the Céline Mary article.

COURT REPORTER: I'm sorry?

MR. THORNBURG: Céline Mary.

(Little Deposition Exhibit 7 was marked

for identification.)

Q. Doctor, before we go there, let me ask you this question. Do you have any opinion one way or the other whether or not Prolene polypropylene mesh devices have better stability than Marlex mesh devices manufactured by Boston Scientific?

MS. STEELE: Object to form.

A. No, I didn't do an analysis of the differences between the two. My analysis was more generally focused on polypropylene meshes as a whole.

Q. Not specific to Marlex or Prolene?

A. Other than commenting on some of the details of Marlex in my report, no.

Q. Do you know what the additives package is in the Prolene polypropylene used by Ethicon or Johnson & Johnson?

MS. STEELE: Object to form.

A. Off the top of my head, I don't remember what they are.

Q. Do you know what design validation studies may have been done by Ethicon to determine the suitability of the antioxidant additives package it chose to use for its Prolene product?

MS. STEELE: Object to form.

A. No, not that I recall, no.

Q. Okay. If you look at Exhibit 7, Céline Mary -- and this is an article that you're familiar with; correct?

A. Yes.

Q. And this is authored by Céline Mary and a number of other scientists including Robert Guidoin?

A. I can confirm that, yes.

Q. Have you heard of Dr. Robert Guidoin before?

A. No.

Q. Have you heard of the Quebec Biomaterials Institute?

A. I have.

Q. Okay. They're a respected biomaterial institute; correct?

A. Yeah. Like I said, I think so.

Q. Okay. And if you look at this -- and this is dated 1998; right?

A. Yes.

Q. And you understand this was a study that -- a preclinical study that compared explanted Prolene to another -- another polymer known as PVDF?

A. Yes.
Q. And you understand, without going into great detail yet -- but you understand that the conclusions of these authors like Wood and like Cozad was that polypropylene material will degrade in vivo?
MS. STEELE: Object to form.
A. I understand that that's the conclusion that they came to when looking at this data, yes.
Q. And this would be more researchers who you would disagree with; correct?
MS. STEELE: Object to form.
A. Well, so I would say that I disagree that it's oxidizing. And I disagree that it's degrading. There's parts of this, I believe, that I agree with where the authors are suggesting that this is biological material on the fibers.
Q. Well, if we look at this, their conclusion actually was that you can have biological material on the fibers but that the polypropylene does indeed undergo in vivo degradation; right?
MS. STEELE: Object to form.
A. Well, yeah, based on these pictures right here that suggest this is biological material.

Again, I disagree with that conclusion, but that's what they concluded.

Q. And if you look at the description section -- the discussion section, sorry, they talk about a stress cracking phenomenon. Are you familiar with environmental stress cracking?

A. I'm generally familiar with the concept. It looks exactly like this biological material. I'm familiar with the concept.

Q. And you're familiar with the concept that when there's a drop in the crystallinity of polypropylene materials, including fibers, that there -- and there can be amorphous zones that are created on the surface and that, for example, estrogenized fatty acids -- I probably said that -- I probably butchered that -- but they can become absorbed into the surface and expand and crack the polypropylene?

MS. STEELE: Object to form.

A. No, what you just said doesn't sound scientifically correct.

Q. Okay. So you would disagree with that?

A. The way you just said --

MS. STEELE: Object to form.

A. -- that right there, yeah, that doesn't -- I guess I'm not understanding, but that doesn't sound scientifically correct to me.

Q. More ionic bonds of -- of esters --

COURT REPORTER: I'm sorry, can you repeat that?

Q. What is -- what is the onic -- ionic charge of esters?

A. Well, I mean an ester bond doesn't have a charge.

Q. It's your opinion that ester bonds don't have charges?

A. Yeah, a normal ester bond is not an ionic bond.

Q. What's an ionic bond of Marlex polypropylene?

MS. STEELE: Object to form.

A. Marlex polypropylene is not -- does not have an ionic bond.

Q. Okay. And let me ask you another quick question; it's a little bit off topic. But did you ask for the design history file -- to review the design history file in rendering any of your opinions in this case?

MS. STEELE: Object to form.

A. No, I don't think so, no.

Q. So you don't know -- have any opinion necessarily about the design history file of the content -- content therein; correct?

A. Not that I --

MS. STEELE: Object to form.

A. Not that I can recall, no.

Q. Did ask you for one?

MS. STEELE: Object to form.

A. Not that I can recall, no.

Q. Okay. If we look at this really quick, and I won't go into great detail here, but do you recall reading that these authors and other authors that they cite discuss a skin/core structure in extruded polypropylene fibers?

A. In the Mary article now we're talking about?

Q. Yeah. And she cites other authors like -- like the scientists Dr. Blais, et al.

A. Okay.

Q. You reviewed the publications by Dr. Blais?

A. Not that I can recall, no.

Q. This paragraph on page 205 of Exhibit 7, the authors write, "The reason for this stress cracking

phenomenon in oriented polypropylene monofilaments has been explained by their pronounced skin/core structure. This bicomponent structure is created by the differential cooling rates between the external and internal layers of the monofilaments during the melt spinning process, which leads to the formation of a low order nonfibrillar outer skin a few microns thick, and a highly oriented the crystalline fibrillar inner core."

Did I read that correctly?

A. Right, so this is what they're speculating in here. They didn't do a study to show this.

Q. Well, they -- they cited some publications; right?

A. Yes, but the speculation based on what they've seen. You didn't do a study where you -- you had any controls where you could make that conclusion. It's in the discussion section, so it's a speculative reason as to why they could have seen what they believe is a cracked surface, which is very clearly biological material.

Q. They cite to other scientists -- they say, "Blais et al. identified a distinct separation and different properties between these two layers.

They found that the outer skin is more susceptible to oxidative degradation than the fibrillar inner core."

You didn't read Blais; correct?

A. I didn't read -- read Blais no.

Q. And so you didn't consider what Blais thought, the work of Blais, and Dr. Blais' findings; correct?

A. No, I disagree with that. I read this page, and what I see is I see them speculating if what they're seeing here on these SEMs is oxidatively degraded polypropylene, which I do not believe it is, they're saying that that could be a possible reason for it; and they cite another article that describes where that speculation came from, but they do not prove that that's what it is.

Q. You haven't proven that that's what it isn't, have you?

A. Well, when you look at all --

MS. STEELE: Object to form.

A. When you look at all of the literature, then you can clearly see the pristine polypropylene fibers underneath of this stuff.

Q. When you -- when you cite to paid

consultants like Dr. Thames and Dr. de Tayrac; right?

MS. STEELE: Object to form.

A. Yeah, I mean, I guess I don't see how you can have eleven-and-a-half-year fiber and then have it -- the surface look exactly like this --

Q. I'm going to show you.

A. -- and then have the -- the piece of it come off in a lock-and-key formation that underneath shows a pristine fiber with the manufacturer's striations.

Q. We're going through the data, aren't we, Doctor? So you're relying on the find- -- the publications by Dr. de Tayrac and Dr. Thames; correct?

MS. STEELE: Object to form.

A. And all of the others that we talked about before, going all the way back to the original article that says that it could be biological material on the surface and that you can't conclusively say that it's --

Q. You've never --

A. -- oxidative degradation.

Q. You haven't identified any others than

Dr. de Tayrac and Dr. Thames --

A. No, I offered --

Q. -- (inaudible).

COURT REPORTER: I'm sorry, I can't hear you.

MS. STEELE: Object to form.

A. That's not correct. I did offer others and I also offered to go into it, and you kept going on and interrupting me.

Q. Okay. So I'm going -- I'm going to have you highlight for me at the end of this the ones that support your opinion. But we'll keep on going.

MS. KROTTINGER: Hey, Dan, we need to change the tape for the video.

MR. THORNBURG: How much time do we have? I'd like to finish this line of questioning real quick.

MS. KROTTINGER: Three minutes left.

MR. THORNBURG: Let's finish this real quick. Let's see how far we can get.

Q. Blais -- they talk about Blais and Blais "identified a distinct separation and different properties between these two layers. They found that the outer skin is more susceptible to"

oxidation -- "oxidative degradation than the fibrillar inner core. Cleavage of the polymer chains causes relaxation of the folded lamellae, increases in crystallinity and density, and contraction localized to the outer skin. This in turn leads to a regular circumferential crack formation at the surface, but only to the depth of the outer layer. Because this cracking is confined to the outer layer (sic), which is clearly distinguishable from the inner core structure, it is not surprising to observe that, during abrasive stresses, such as cleaning, there was a tendency for the cracked rings at the surface to flake off and separate from the underlying core material."

Did I read that correctly?

A. Yes. But I would just say --

Q. And --

A. I would just say that all of this is the same thing that you would expect to have happen if you had biological material on the surface. You would see the same thing.

Q. Did Dr. Thames remove the outer layer in his cleaning protocol that he used?

MS. STEELE: Object to form.

A. I'm sorry, I'm not understanding your question.

Q. Would you -- would you agree with me that the protocol that Dr. Thames and Dr. Ong established, and which they cite to in the publication we looked at a moment ago, shows a -- an abrasive cleaning procedure?

MS. STEELE: Object to form.

A. No.

Q. Do you know if Dr. Thames ever analyzed the outer layer after it was removed to determine whether or not he was removing degraded oxidatively -- or oxidatively degraded polypropylene?

A. Yes.

Q. What -- what studies can you -- strike that.

I've taken the deposition of Dr. Thames; I'm very familiar with his work. He has never collected the polypropylene material or the material that was removed during his studies and tested them to -- to validate that he wasn't removing degraded polypropylene.

MS. STEELE: Object to form.

Q. Right?

A. Well, he -- are you putting that testimony in, or is that a question?

Q. Well, for example, there's a -- there's an ASTM protocol concerning collecting the particulate matter from surface -- polypropylene surfaces that are being cleaned and a guideline to be followed to not only collect but also to test the removed material to determine whether or not the material that was removed was degraded polypropylene. You -- you understand that there's an ASTM concerning that exact issue; right?

MS. STEELE: Object to form.

A. Sure, but he checked the composition each time he did the cleaning procedure, so you're seeing what material was taken off and what's underneath of it each time he cleaned.

MS. KROTTINGER: Hey, Dan, we have to go off.

MR. THORNBURG: Okay. We'll go off now.

THE VIDEOGRAPHER: We're going off the record. The time is 12:32 p.m.

(Whereupon, a recess was taken.)

THE VIDEOGRAPHER: This is the beginning of disc three. We are going back on the record.

The time is 12:43 p.m.

BY MR. THORNBURG:

Q. Dr. Little, before we took a quick break, we were discussing the Mary article; right? Correct?

A. I thought we were discussing the Thames article before the break.

Q. We were talking about it in the context of the Mary article, specifically the paragraph by Dr. Mary and her colleagues on page 205 that discusses how explanted polypropylene, as a result of the oxidative degradation process that happens in vivo, can cause the outer degraded layer to crack and flake off and separate from the underlying core material during abrasive cleaning processes; right?

MS. STEELE: Object to form.

A. What -- I disagree that that's what's happening, but okay.

Q. You disagree with the Mary article; right?

A. Well, so --

Q. You disagree -- let me ask a better question.

You disagree with the conclusions by Dr. Mary and her colleagues; correct?

A. Some of them.
Q. Including the opinion that the polypropylene material degraded in vivo; right?
A. Yeah, but, I mean, she also said that there's biological material on there, so.
Q. Right. But she's not suggesting that they have to be mutually exclusive; right? I mean, you can have biological material and also have degradation.
A. You -- you -- it is possible for you to have biological material and degradation; but if you have biological material on there, you may not be able to detect any degradation.
Q. And it's your opinion that -- and by the way -- strike that.

You understand that the authors of the Mary article cleaned the tissue from the explants; right?

MS. STEELE: Object to form.

A. No, so they -- they admit in this article that this -- there could be biological material on it. So they go through a procedure, and they admit that it's -- there's still biological material on there. So it's the -- it's the definition of

clean. So if you take it through a cleaning procedure, that does not mean that all of the biological materials are off. And many authors explicitly state that, including Mary.

Q. Well -- and Mary, if you look at the "Morphologic and Chemical Studies," there's a cleaning procedure that's described; correct?

A. So there's a procedure that is discussed here. It -- it should be noted that when you say cleaning procedure --

Q. My question to you --

A. -- that does not mean that it's clean --

Q. With all due --

A. -- but it--

Q. With all due respect, Doctor, this is going to be a long day if you don't answer my question. My question was simply, the Mary article outlines, on page 200, the cleaning procedure that they used; correct?

A. No. They do not say cleaning procedure.

Q. Well, look at -- look at Exhibit 7. Okay. Are you there? On page 200? Bottom right-hand corner.

A. I'm not with you, I'm sorry.

Q. What are the bolded -- what are the bolded words?

MS. STEELE: Dan? Dan, he's just -- we're --

A. I'm not --

MS. STEELE: Where are you?

A. Page 200.

MS. STEELE: Of Exhibit 7.

A. Of Exhibit 7. Okay.

Q. And what are the -- what are the bolded words on bottom right-hand corner?

A. Sorry, I was in another article. So it says here, "Cleaning procedure."

Q. Okay. And they discuss the procedure that they used to clean the explanted PVDF and Prolene sutures; correct?

MS. STEELE: Object to form.

A. They describe a procedure that they use to remove -- an attempt to remove material, yes, but they say in there that not all of the biological material is removed.

Q. Okay. And they actually talk about, in the very first sentence, they say this was a -- they used a technique that they established in their

laboratory; right?

A. Yes.

Q. And they used "special care...when handling the sutures during this cleaning process." You think that's important; don't you?

MS. STEELE: Object to form.

Q. Do you agree it's important to use special care when handling specimens that are being studied?

MS. STEELE: Object to form.

A. Well, it depends on what you mean by special care. But, yes, generally, scientists would, you know, try not to drop something. Yes.

Q. You don't want to contaminate the product; right?

A. Sure.

Q. If she's correct about the skin/core morphology and that degraded polypropylene surface material will break away from the inner core, that's another reason why she'd want to be careful in handling the material; right?

A. Well, so --

MS. STEELE: Object to form.

A. So she -- the -- your question has

assumptions in it that I don't agree with. I do not agree that she proved that that's what's going on. It was a speculative thing that was put in the discussion section as to one possible reason as to why. The study was not done.

Q. She exposed both the PVD -- I'm sorry, the PVDF suture and the Prolene sutures to the same cleaning process; right?

A. I believe so, yes.

Q. And that's important; right? She's comparing the Prolene to PVDFs to prepare the studies, so you have to treat them the same; right?

A. Depending on what you're trying to conclude, yes.

Q. When you're comparing the changes to the -- to the surface area of two of these sutures after explantage from animals; right? Correct?

MS. STEELE: Object to form.

A. Could you repeat that question, please.

Q. She is -- you understand that she treated the PVDF the same way she treated the Prolene?

A. Yes.

Q. Okay. And the -- you understand that they found that after one year and two years the

polypropylene was more degraded than the PVDF; right?

MS. STEELE: Object to form.

A. Well, they show more -- they show more material on the surface which is what you would expect from a fiber that is very good at promoting ingrowth of tissue. Right? So that -- they show that. Their conclusion ultimately is they say that there is degradation. I just disagree with that conclusion based on the data.

Q. Okay. And they're comparing two different polymer sutures; correct?

A. Yes.

Q. Under the same environment; right?

A. Yes. Correct.

Q. And the same cleaning protocol; correct?

A. Correct.

Q. Yet they didn't find adhered biological material surrounding the PVDF fiber like you claim they found surrounding the Prolene fiber; correct?

MS. STEELE: Object to form.

A. Yep, that's right, and that's one of the reasons why people use polypropylene fibers is that they're better for getting the biological material

in there.

Q. In where? These are fibers.

A. That's right. So it's coating the surface, and the surface of polypropylene is hydrophobic. It's one of the most hydrophobic materials that is used in bio -- biological applications and biomaterials applications. So it's going to be better at getting that protein coat on the surface which dictate -- dictates all kinds of downstream events.

Q. And what's the surface of the PVDF?

A. I'm sorry, what's the surface of it?

Q. Is it hydrophobic as well?

A. Well, I mean, it's going to have a particular hydrophobicity, but what I'm saying is, is that the polypropylene has -- and it's one of the reasons that it's chosen for this -- it just has this combination of properties that makes it better for infiltration of cells and tissue.

Q. Okay. So you understand we're looking at suture material here; right?

A. Yes.

Q. And do you know what PVDF is?

A. Yeah, it's polyvinylidene fluoride.

Q. Have you ever studied PVDF?

MS. STEELE: Object to form.

A. I mean, I'm aware of the material, yes.

Q. Are you aware that PVDF is a material that's used in mesh material?

A. Yes.

Q. Okay. And are you aware of the publications that demonstrate, time and time again, that PVDF is a more stable material than Prolene?

MS. STEELE: Object to form.

A. No, I don't think I would agree with that assessment.

Q. Well, did you read any publications other than Mary that talked about PVDF?

A. Well, what I -- what I'm saying is, is that the -- that polypropylene has been chosen for this application specifically, and there have been comparisons to other materials, but ultimately polypropylene is the one that's chosen. And it's for, amongst other things, because it's very good at promoting infiltration of tissues and cells.

Q. Have you ever chosen a polypropylene suture over a PVDF suture to be implanted in any patient?

MS. STEELE: Object to form.

A. No, I mean, I'm not a medical doctor. I did not do that, no.

Q. Okay. You understand that there are PVDF sutures, don't you?

A. Sure.

Q. Okay. And you understand that there are doctors that use PVDF sutures in their patients?

A. Sure.

Q. And you understand that there are medical device manufacturers who place on the market PVDF sutures to be used by doctors in treating their patients; right?

A. Yes.

Q. And have you looked at any of the stability studies that have been done -- I'm sorry, not stability studies -- strike that.

Have you -- have you looked at any of the tensile strength studies that have been done on explanted Prolene sutures?

MS. STEELE: Object to form.

A. You know what, actually there's -- there's not a whole -- from what I've seen, not a whole lot of mechanical property testing of the explants that we're talking about, these meshes. You just don't

see people doing mechanical testing.

Q. Well, you didn't cite to any, did you?

MS. STEELE: Object to form.

A. Well, I mean there's, for instance, a test that was done in Costello where -- I cite that one. But I actually think that that test reinforces my opinion in this matter, so.

Q. Did you -- can you -- did you rely on any tensile testing done to render your opinions that polypropylene does not undergo in vivo degradation?

MS. STEELE: Object to form.

A. Other than what I cite in my report and in my materials considered list, those are the things that I considered.

Q. Have you ever performed tensile stress testing?

A. I've been in -- I've been involved in the performance of tensile strength testing. I know how it works. I haven't specifically done that in my papers, no.

Q. Okay. And so you can do -- you understand that there are researchers who have done tensile stress testing on pristine polypropylene sutures and compared the tensile strength to explanted

polypropylene sutures?

MS. STEELE: Object to form.

A. I'm sorry, is that a question?

Q. Yes. I mean, the Mary articles goes -- provides significant description of some of those studies that found that, when compared to pristine polypropylene sutures, explanted polypropylene sutures broke -- or maintained only approximately 50 percent of the -- what the tensile strength of -- was of a pristine.

MS. STEELE: Object to form.

Q. What would that -- that type of finding suggest to you?

A. Well, so, I mean, I guess I would -- I would need to look at that study. I know that whenever you have -- if you don't properly clean the sample, then you're going to get different properties of the material, and you sort of see that in Costello.

Q. So you believe that if you don't properly clean an explanted suture -- polypropylene suture material and perform a stress test on it, that the -- it won't maintain the same tensile strength as a pristine; is that your opinion?

MS. STEELE: Object to form.

A. Well, specifically with tensile strength, I could -- I could spend some more time looking at this. I -- I can tell you that if you do have stuff coating the outside of it, it's going to change the mechanical properties in the material.

Q. Is it going -- is it going to change -- what studies have you performed to determine whether or not it would change the tensile strength of a material?

MS. STEELE: Object to form.

A. I didn't perform studies, but I'm just saying that if you have biological material like a plasticizer or something that is stuck on the outside of the material, it would change the tensile properties. It would change the mechanical properties.

Q. And that's your personal opinion based on --

COURT REPORTER: I'm sorry? I'm sorry?

Q. That's you -- sorry. That's your personal opinion, Doctor, based on what?

A. Well, it's just based on I know in, you know, basic material science, that if you add a plasticizer, it changes the mechanical properties. If you were to coat the outside of it with

something, it would change the mechanical properties.

Q. Will it change the mechanical properties in such a way that it reduces the tensile strength?

MS. STEELE: Object to form.

A. Yeah, I mean, I'd have to look at the specific study to see what you're referring to, but I can imagine a situation where, if you add biological material, it could change things, yes.

Q. Okay. But you haven't looked at those specific studies; correct?

A. No, I didn't -- I didn't look at the specific study, no.

Q. So you're not going to offer testimony at trial regarding tensile strength other than what's in your expert report?

MS. STEELE: Object to --

A. I would just say that -- that I will offer testimony that the mechanical properties testing that I've seen in the papers that I -- that I have in my -- I mean, I cite them in my report, those tests suggest that it's not degrading.

Q. But -- but that's not specific to any tensile strength analysis; correct?

A. Yeah, I'm not -- I'm not remembering the specific test that you're talking about, no.

Q. So my question is -- look, this is my only opportunity to ask you questions before you appear at trial.

You're not going to go and suddenly appear at trial and have opinions about tensile strength testing?

MS. STEELE: Object to form.

Q. Correct?

A. Well, I mean for instance, I will -- I will talk about, potentially, the compliance testing in Costello, how that supports my opinion; the mechanical property testing in Liebert, how that supports my opinion, but I'm -- I would imagine I'm not going to refer to the specific study you're talking about because I -- it's not in my report, and I didn't feel like it was important for my -- my conclusions that I made. So I probably won't talk about that.

Q. Do you agree that all polypropylene degrades at some rate?

MS. STEELE: Object to form.

A. Well, I think -- it's an interesting

question; right? I mean, it's almost like a meaningless question because like everything in the universe degrades at some rate, so.

Q. So the answer to my question is yes?

A. Yeah, everything in the universe would be chemically reactive to some degree.

Q. Including Boston Scientific's polypropylene Marlex meshes; correct?

MS. STEELE: Object to form.

A. Well, what I'd say is that I -- I would say that's true if you heat it up. I don't think that it's reacting in the human body.

Q. Do you agree that the primary and secondary stabilizers only slow the degradation rate; correct?

A. Yeah, again, it's almost like a -- I just say, it's like a meaningless question; right? I mean it's --

Q. It's a yes or no. Do you agree with it or not?

A. Yeah, I mean, it slows the degradation, that's the purpose of it. Yes.

Q. Do you agree that more than any other -- strike that.

Do you agree with me that antioxidants are sacrificial stabilizers utilized in the production of Marlex HGX-030-01 and other polypropylenes and are consumed over time?

MS. STEELE: Object to form.

A. Yes, so there are multiple layers of antioxidants that, you're correct, they do get consumed over time. The question is, what time are you talking about and what conditions you're talking about as to whether they're consumed to any meaningful degree.

Q. You understand that there are many different types of stabilizers; right?

MS. STEELE: Object to form.

A. I mean, I guess -- yeah, I mean, there's different kinds of stabilizers.

Q. And each stabilizer has a different purpose; right?

MS. STEELE: Object to form.

A. Well, yeah, I mean, I would say that when manufacturers add them, they add them with a specific purpose. It's possible that they can have multiple effects. But, yeah, I mean, that's why they're added is for a specific purpose.

Q. Can you explain to the ladies and gentlemen of the jury what a primary stabilizer is.

A. Sure. I mean, a primary stabilizer is -- it basically takes on a radical. So if there is a radical that exists that could be reactive, it takes it on and then basically displaces it so that it's not in any one particular location on the molecule. So the result is, is that the molecule that takes on the radical is not reactive.

Q. Do you know what the primary stabilizer is in Marlex HGX-030-01?

A. Yeah, it's in my report. We were talking about it earlier. It's Irganox.

Q. Okay. Irganox 3114?

A. Yes, 3114.

Q. You understand, don't you, that Irganox 3114 is not a long-term thermal stabilizer?

MS. STEELE: Object to form.

A. Again, you've got to define like long-term and what you're talking about. Again, you know, are we at high temperatures that -- temperatures in the body? But, you know, you're right, it -- under high temperatures, for instance, it will be consumed at one point.

Q. And what temperatures are used during the manufacturing process of Boston Scientific's Marlex devices?

MS. STEELE: Object to form.

A. Well, it would be over the melting temperature which is going to be like 160, realistically. So it's over that. The specific temperature --

Q. For the record, 160 what?

A. Degrees Celsius.

Q. Okay.

A. And, you know, there's other -- as I show here, there's other antioxidants that are put in there, and one of the reasons is that -- so that it protects the primary antioxidant during the manufacture.

Q. Can you explain to the ladies and gentlemen of the jury what a secondary stabilizer is.

A. Sure. So a secondary stabilizer -- in this case it's Irgafos 168 -- it can deactivate a -- basically a chemical group that's produced during an oxidizing event. So if it gets -- another way to say this is that if it gets past the primary antioxidant, there's a layer behind it to stop the

thing that gets produced from that event.

Q. Okay. And what is the secondary stabilizer in Marlex HGX-030-01?

A. It's Irgafos 168.

Q. Okay. And you testified a moment ago that polypropylene won't degrade in the human body because it's not exposed to light or heat; right?

MS. STEELE: Object to form.

A. Yes. So it's, you know -- the kind of conditions that degradation is studied is like at least 200 degrees C, so you don't see anywhere near those temperatures in the body.

Q. Okay. But you also cite to the Liebert article, don't you?

A. Yes.

Q. And the Liebert article involved a preclinical study where unstabilized polypropylene and stabilized polypropylene were implanted in hamsters; correct?

A. Yes.

Q. And what's the temperature inside a hamster?

A. Well, it's going to be close to 37 degrees Celsius.

Q. Okay. And there are -- there's blood and

free radicals and other biologic material like humans; right?

A. Well, yes, so there's -- there's concentrations of things. The concentration of the stuff you're talking about like free radicals is very small.

Q. And despite that, the polypropylene sutures that were implanted in the hamsters that weren't stabilized degraded; right?

MS. STEELE: Object to form.

A. What number is this?

MS. STEELE: Do you want to mark it?

Q. Sure, we can mark it. I didn't think you needed to mark it; it's in your expert report. I mean, if your testimony is that polypropylene won't degrade inside the human body because it's not exposed to UV or heat, then the polypropylene that was implanted -- the unstabilized polypropylene that was implanted in hamsters wouldn't have degraded?

A. Well, you know, it's -- one of the things I mention in the report here is that, you know, you're basically using this FTIR signal, which is just looking at the surface, to say that you're

seeing this C double bond O signal. And, you know, if you -- if you correlate this to the mechanical testing, during this rapid period of increase in these bonds that they're saying are degraded products, you see no change in mechanical properties.

Q. Doctor, hold on a second. That -- that didn't answer my question whatsoever.

My -- you made a suggestion to the ladies and gentlemen of the jury that polypropylene won't degrade inside the human body because it's not exposed to UV and it's not exposed to excessive heat. That was your opinion. That was your statement to the ladies and gentlemen of the jury; right?

A. No, you --

MS. STEELE: Object to form.

A. -- you put words in my mouth.

Q. Well, the record will speak for itself Doctor.

But isn't it true that Liebert's study demonstrated that there are oxidative species in the body that will degrade polypropylene if it's not adequately stabilized?

MS. STEELE: Object to form.

A. So first of all, what I'd say is that my comments about polypropylene not degrading are very certain related to the stabilized polypropylene formulations. Liebert, for instance, shows that stabilized polypropylene here does not degrade at all.

Secondly, when it comes to non-stabilized polypropylene, which is where you are now in taking my statement before and using it, what I'm saying is, is that in this particular case, there are pieces of information in this paper that are very curious.

So you're seeing, for instance, an increase in signal, which we have talked before about there could be other reasons that you would have an increase in signal on the surface. During that rapid increase in FTIR signal, you see no change in mechanical properties. So what that tells me is that it can't be degrading the material if you have this rapid increase in signal and it's not changing the material properties.

Q. What paper are you talking about? You said in this paper.

A. Liebert's.

Q. I want the record to be clear. Okay.

So are you suggesting that Liebert's conclusions were incorrect?

A. I'm saying that there -- yeah, I mean, I'm saying that there are, A, the signal that you're seeing on the surface with FTIR, you can't necessarily conclude that it's degraded polypropylene; and, B, there is some very curious things in here like the mechanical properties not changing during this rapid increase in signal that's on the surface. So there are things in here that would indicate to me that it's not degrading.

Q. So when they performed a study, they compared a stabilized polypropylene to an unstabilized polypropylene as a control; right?

A. They looked at both of them, yes.

Q. Both of them were implanted in animals; right?

A. Yes.

Q. They were -- they were treated the very -- the exact same way. That's good science; right?

MS. STEELE: Object to form.

A. Well, they're -- they're -- they're treated

in the same way, yes.

Q. They were in the same in vivo environments; right?

A. Yep, according to the paper.

Q. Okay. And when they -- when the -- when both materials that were treated the same way in the same environments underwent testing, the -- there were differences in the controlled specimen, the uncontrolled -- the unstabilized polypropylene compared to the polypropylene specimen; right?

MS. STEELE: Object to form.

A. Well, changes, yes. There were some changes according to one variable, yes.

Q. Okay. And not just one variable; there are a number of variables?

A. Yeah. And then there's also what I just described to you, which is that when you see the changes in the variables you're describing, you see no changes in the material properties.

Q. There were -- the mechanical testing looks different between the two products. You keep on suggesting that the mechanical -- mechanical --

COURT REPORTER: I'm sorry. I'm sorry.

Q. Yeah. Strike that.

Dr. Little, you keep on suggesting that the mechanical testing that was performed demonstrated the same results, but that's not correct.

MS. STEELE: Object to form.

A. Could you please describe? I'm not following you.

Q. Okay. You're familiar with this article; right?

A. Yes.

Q. Okay. And the mechanical testing that was done demonstrated that there were changes and differences between the unstabilized and stabilized polypropylene fibers when they performed mechanical testing.

MS. STEELE: Object to form.

A. No, I mean, I'm looking at page 949 where they're saying that you should see changes in the mechanical properties, and you don't. If it's degrading.

Q. Under the results section?

A. On page 949.

Q. 949. Okay.

A. It's in the discussion section.

Q. Okay. Point to me where you're -- you have an issue with this article.

A. Well, it's not my issue. It's their issue they bring up. So it's in the second paragraph. You could start about halfway down and read to the end of the paragraph.

Q. That's not the mechanical testing.

A. Tan delta?

Q. Where you -- that is not tensile stress testing; correct?

A. Well, tan delta is --

Q. That's a --

A. Sinusoidal tensile strain, it's applied to the end of the sample. Phase angle delta between the applied strain and resulting stress is measured.

Q. Yeah, but the -- so if you -- if you finish the page onto 950, they discuss on page 949 that there were actual changes that they observed in the unstabilized polypropylene.

A. Yeah, but it's not --

Q. You're referencing one data point, but they -- they describe multiple data points --

A. No.

Q. -- that demonstrate changes.

A. No, what they say is that you would expect to see the change in tan delta when the carbonyl groups are formed. So what you see is that at the beginning you see some change, right, but then you don't have any of these carbonyl groups. When the carbonyl groups are appearing, you see no change.

Q. At that time point.

A. That's when they say you should see it.

Q. Well, at that one time point in the study, what they're referencing with respect to one data point for a tan delta; correct?

MS. STEELE: Object to form.

A. They do tan delta, what, at one, two, three data points. So it's two data points that show -- confirm that there's no change.

Q. They do -- they do GPC on the -- on the unstabilized material; right?

A. Are we talking -- wait.

Q. On the same page, 949.

A. 949. Okay.

Q. And there were differences between -- in the GPC data that they observed in the unstable versus the stable; right?

MS. STEELE: Object to form.

A. Well, they're -- they're talking about this here, but that's on Figure 5, so if you look at that Figure 5, that's just basically two overlapping curves.

Q. There's a -- you can see a difference on 946. They're not -- they're not perfectly overlapping; correct?

A. Yeah, I mean, they look to me like they're overlapping.

Q. Okay. And the FTIR data demonstrated a difference between the unstabilized versus the stabilized; correct?

MS. STEELE: Object to form.

A. Yeah, I mean, we've talked about that.

Q. And it showed according these authors oxidatively degraded polypropylene in the unstabilized suture; correct?

MS. STEELE: Object to form.

A. They are saying that that could be indicative of that, but we've talked about how that could be other things; and most importantly, they say in this paper that you would expect to see changes in mechanical properties. And you don't.

Q. So you believe that neither the unstabilized nor the stabilized polypropylene fibers that were implanted in these rats in the Liebert study demonstrated degradation?

MS. STEELE: Object to form.

A. Material degradation, no. That's -- that's unquestionable because you see no change in the material properties. What's --

Q. Was there --

COURT REPORTER: I'm sorry?

Q. Was there oxidative degradation?

A. Well, so if you're saying degradation of the material, no. If there was any changes on the surface -- I mean, you're detecting some change on the surface with FTIR, but it's not degradation because it's not change in the material properties. So you're seeing something. It's not change in material properties, so it's not degrading the material.

Q. If you look at the conclusion section on page 950. Right? Are you there?

A. Yes.

Q. Okay. The paragraph 1 discusses these authors' opinions that the unstabilized

polypropylene degraded as a result of oxidative degradation; correct?

MS. STEELE: Object to form.

A. Where are you?

Q. On 950, the first paragraph under conclusions. Number 1.

A. It -- okay. So the following is a summary of the findings. Okay.

Q. Then they discuss the carbonyl groups were observed to form after 99 days of implantation. The induction time was determined to be approximately 108 days using their formula; correct?

A. Well, right. So, you know, there's two things you just said. One of them is that you have some change in the surface signal, which we talked about, and that doesn't necessarily indicate that the material is degrading. And more so in this paper, it can't be the material degrading because you don't see changes in the physical properties. Then the next piece --

Q. If you look at --

A. -- was the -- you're saying that there was a formula that's used. Right. So that's, then, a

theoretical calculation that they're performing that's based on their data.

Q. Number 4, "Dynamic mechanical tests of implanted filaments show that the rigidity increases during the first 30 days of implantation but remains constant throughout, up to the last limit of 150 days."

And that's the issue that you have -- you find the most support in your opinion that neither the unstabilized or the stabilized polypropylene degraded in this study; right?

MS. STEELE: Object to form.

A. Well, yeah, I mean, they're the ones that are putting it forth.

Q. But they actually say that there was a decrease -- there was an increase but then that increase stopped over time; correct?

A. Well, right, but we just read that. So it says where you should see the increase if it's degrading is when the signal increases, which is what you don't see.

Q. And then you disagree with paragraph 5, I assume, because the authors conclude that the infrared spectra and mechanical testing of

implanted and nonimplanted filaments containing an antioxidant showed no changes in the chemical and physical properties as a result of implantation. "These results" -- and this is where I think you disagree -- "these results support the view that the changes observed in pure implanted -- meaning the unstabilized filaments -- are due to oxidative -- oxidation rather than diffusion or other known effects of the antioxidant specifically inhibits and/or retards oxidation."

A. Well, I think that what this is is it's saying that you might conclude that because in the one you have an FTIR signal that's different, that the antioxidant could be responsible for that effect. I think that's what this is saying, but when you put all this together, you know, the material can't be degrading if I'm understanding this correctly and they're showing everything because, you know, how do you have increases in that signal and no changes in the mechanical properties.

Q. Well, but you have increases in the signals of both polypropylene specimens that were treated the same way, yet in the unstabilized suture you

have a change in the FTIR; right?

MS. STEELE: Object to form.

A. Yeah, I mean, we talked about this. You're talking -- you're talking about one piece of data, and in that one piece of data, it's different. And that on its own I don't think is enough to say that it's degrading, but in light of all of the rest of the data, I think you can say that it is not.

Q. And this was at how many days of implantation, 108 days?

MS. STEELE: Object to form.

A. Well, I mean, they're including implantation times of, what, 150 on these plots?

Q. So at 150 days -- they concluded that after 150 days there was some evidence of oxidative degradation in the unstabilized polypropylene?

MS. STEELE: Object to form.

A. Did you say they conclude?

Q. They concluded that there was some evidence of oxidative degradation in the unstabilized polypropylene material; correct?

A. Right. So some evidence, and in that they're specifically referring to this FTIR signal which could not be correlated to any changes in the

material properties.

Q. Do you know what a phenolic is?

A. A phenolic, I mean, I know the group, yes.

Q. Explain what a phenolic is?

A. Well, I mean, it's an aromatic ring that has a hydroxyl group.

Q. Do you agree that phossohites (phonetic) are used during processing of the Marlex device product to help limit the amount of primary antioxidants that are consumed during processing?

MS. STEELE: Object to form.

A. Yeah, I'm sorry, I'm not following you. What --

Q. Will you agree that in manufacturing any sort of polypropylene material, like a suture, do you agree that phossohites are used during processing to help limit the amount of primary antioxidants that are consumed during the processing?

MS. STEELE: Object to form.

A. I'm sorry, I don't understand all the words that you said in your question.

Q. Okay. So you -- you can't answer that question as phrased?

A. I can't answer it because I don't understand. Maybe it's the phone, but --

Q. Do you know if phossohites are used during processing of --

A. Could you spell that word?

Q. -- polypropylene sutures or polypropylene mesh material?

A. I'm not familiar with the word.

Q. Okay. So you have no opinion one way or the other regarding phossohites?

A. No.

Q. And you don't know the concentration contained in Marlex used by Boston Scientific of the -- of the different antioxidants; correct?

MS. STEELE: Object to form.

A. No, not off the top of my head, no.

Q. And that has no import in your opinion?

MS. STEELE: Object to form.

A. What I would say is that I have not done the analysis to determine the amounts or the ranges or the acceptability, so I don't have an opinion on it.

Q. Are there any additional stabilizers that are added during the processing of Marlex?

MS. STEELE: Object to form.

A. I'm pretty sure there's another antioxidant that we haven't talked about that's in there. There's three.

Q. Okay. We -- I thought we talked about Irganox; right?

A. Yes.

Q. We talked about Irgafos; right?

A. Yes.

Q. And is the other one DHT-4A?

A. Yes.

Q. And is DHT-4A a primary or secondary stabilizer?

A. Um, I --

MS. STEELE: Object to form.

A. I think that the purpose of it in this, in this specific example is it scavenges things that would activate the materials that could be produced during a reaction event. So there are acids, for instance, that would potentially activate the species that we talked about that are produced in the secondary antioxidants instance. So it scavenges those.

Q. Which one of the stabilizers that we've

discussed -- the Irganox, the Irgafos, or the DHT-4A -- provide long-term stability in vivo?

A. Well, they would all provide stability. I think, you know, you're talking about long-term, I mean, they're going to provide stability on top of the stability that polypropylene would already have.

Q. Do you know how long the Irganox, Irgafos, or DHT-4A would provide stability in vivo?

A. No, I don't have an opinion on that.

Q. Do you know if any one of these antioxidants were specifically used to prevent in vivo oxidation?

MS. STEELE: Object to form.

A. Well, I mean, they're all going to play a role in inhibiting in vivo oxidation.

Q. Would you agree that inadequate stabilization can create degradation during processing?

MS. STEELE: Object to form.

A. I think it probably depends on the processing. But I didn't spend time looking into that, so I don't have an opinion.

Q. Do you agree that degraded polypropylene can

become embrittled?

A. Well, I don't know. I mean, today you're talking about things where you've got materials diffusing in that could serve as plasticizers, so it may not embrittle, but, I mean, I know that there have been theories that have been put forth about loss of amorphicity and increase in stiffness.

Q. Okay. Have you studied those and will you render any opinions about those in -- or at trial?

A. Yeah, I mean, I think what I would say is that you would see increased stiffness with coatings of biological materials. So you would not be able to tell the difference as to whether or not any increased stiffness or decrease in compliance or any of these other mechanical tests that would suggest that the material is stiffening is because of any oxidized -- oxidizing of the material itself or coating of other biological materials.

Q. You understand, though, that when polypropylene degrades, it becomes embrittled; right?

A. Well, so I haven't seen -- first of all, I haven't seen any evidence of degradation of

polypropylene in the body. I've seen studies where people have said that it's stiffer and less compliant when it comes out, but they've said that about other polymers in the exact same paper that don't even have the bonds that are claimed to be susceptible to degradation here. So clearly in those cases, it's not because of degraded polypropylene because it's happening in the other polymers.

If you're talking about thermal oxidation, I know that there are studies done well over 200 degrees C where, you know, I guess the polypropylene is even above its melting temperature, so.

Q. So it would -- it would actually melt above 200 C; right?

A. I'm sorry?

Q. The Marlex polypropylene would melt at 200 C; it wouldn't embrittle?

A. Well, I mean, the studies are done on very high temperature. I'm not aware of the specific details, but I can tell you that at those temperatures, you know, you might even have phase changes of the polymer itself. I mean, molecular

oxygen has a different energy to react with the material. And there's so many differences. It's -- it's like a different universe.

Q. In your report you actually talk about OIT. Do you recall that?

A. Um, OIP?

Q. OIT? You just testified, I think consistent with your report, that 200 degrees Celsius does not apply at body temperature; correct?

A. Correct.

Q. Does DSC use OIT to determine shelf life stability? Do you know what I mean by OIT?

A. No, I'm not -- I'm not remembering the part of the report that you're referring to. Could you point me to that, please?

Q. Yeah. Hold on one second. Do you know -- I'll strike the last question.

Do you know how Boston Scientific has validated the shelf life stability of poly- -- of this Marlex polypropylene?

MS. STEELE: Object to form.

A. No, I'm sorry, I don't recall.

Q. And the melt temperature of polypropylene is like 164 degrees, correct, 160 -- 160 to 165

degrees Celsius?

MS. STEELE: Object to form.

A. Well, I mean, that's the melting temperature of pure polypropylene. It's like 170, but in -- realistically, by the time you account for some imperfections, it's like 160. But, you know, whenever you have the -- because, remember, the resin is like a met- -- it's like a combination of a bunch of things. So I don't recall specifically what the melt -- melting temperature of that is.

Q. You agree with me that polypropylene, including the Marlex, is not stable at the melt temperature, whatever that is? 160, 165 degrees Celsius, whatever the melt temperature is, you'd agree that polypropylene is not stable at that temperature; correct?

MS. STEELE: Object to form.

A. I'm not sure I have the information as to whether or not to say that's the case.

Q. Do you agree that polypropylene will degrade at room temperature particularly in the presence of UV light?

A. Well, so I know that UV light, yes, can impact degradation kinetics of polypropylene.

Q. Do you understand that polymer stability at melt temperature is required to generate a fiber?

MS. STEELE: Object to form.

A. I understand that some level of stability would be required to get a melted fiber because you have to melt it to extrude it. But, you know, "stability" is sort of a relative term, so it depends on what you mean by that.

Q. Now, in your expert report you talk about the Chevron MSDS warning that the Marlex should not be used in the human body?

MS. STEELE: Object to form.

COURT REPORTER: I'm sorry, I didn't hear you.

Q. Yeah, on page 12 you discussed the material data sheet for Marlex HGX-030-01; correct?

A. Yes.

Q. And in that section, you discussed the material data sheet -- sheet in V warning contained within the MSDS that Marlex resin should not be used in a human body.

MS. STEELE: Object to form.

A. Well, I mean, I do talk about that MSDS, yes.

Q. And we have already established you're not an expert in designing polypropylene; right?

A. Well, I mean, I -- designing polypropylene, I'm not sure I know what you mean by that. I mean, I certainly am educated pretty heavily in polypropylene. I know its uses. It's a biomaterial that is discussed very commonly in my field.

Q. You've never designed it, you've never authored publications on it, you've never spoke about it at presentations or lectures, you've never authored any publications on it, and you haven't even looked at the design history file concerning the Marlex mesh manufactured by Boston Scientific; right?

MS. STEELE: Object to form.

A. So we've talked about this. I -- I don't have experience in the specific design considerations for the mesh. I know the polymer well. I know the biomaterial well. So I think that that's what I needed to make the conclusions in my report.

Q. You're not experienced in determining what the appropriate additive package is for

polypropylene mesh devices; correct?

MS. STEELE: Object to form.

A. No, I haven't done that, no.

Q. Would you agree that determining what the appropriate additive and the quantity of those additives should be -- in a permanent implantable device should be left to experts who have that experience and are at a comfort level in determining additive formulations?

MS. STEELE: Object to form.

A. I mean, I would -- I would say that the final details of exactly how much to add could be something that somebody does who has experience in determining what the additive packages are, the testing associated with it. I would imagine that somebody who had that experience would do that.

Q. And would you agree or do you have the expertise to offer any opinion that when selecting the appropriate additive and the appropriate -- appropriate quantity of the additives to be used, should take into consider -- consideration the intended use of the polypropylene fiber?

MS. STEELE: Object to form.

A. I think it -- it probably depends on the

circumstance that you're referring to.

Q. Do you think that the use, the type of -- strike that.

Do you have the expertise to determine the appropriate quantity of additives and the type of additives that should be used in a permanent medical device?

MS. STEELE: Object to form.

A. I think -- I think it's going to depend on the circumstance and the tolerance and the type of things and the specific application you're talking about. So I don't have an opinion on it. I -- I could look into that, but I have not.

Q. Do you know if Boston Scientific conferred with Chevron in the formulation of Marlex HGX-030-01?

MS. STEELE: Object to form.

A. You're asking me if they conferred?

Q. Yes, do you have any information, did you look at any materials or have any discussions with anybody from Boston Scientific to determine whether or not they met and conferred with Chevron to determine what the appropriate additives formulation ought to have been?

MS. STEELE: Object to form.

A. I mean, I know that they were talking, but the details of which you're referring to, I'm not offering an opinion on that.

Q. Have you reviewed any depositions from any Chevron employees?

A. I think that I, at one point in time, reviewed a deposition from somebody who was in product development from Chevron talking about the MSDS.

Q. When would you have done that?

A. Probably last year.

Q. Do you know if Boston Scientific ever did any testing whatsoever to determine whether or not the Marlex resin would break down and degrade inside the human body before they placed it on the market?

MS. STEEL: Object to form.

A. I don't recall looking into the details of that, no. I don't recall.

Q. Would you agree that Chevron, the manufacturer of the Marlex resin, the supplier of the Marlex resin would be the expert on the additives and the purpose of the additives it used?

MS. STEELE: Object to form.

A. Well, they would be an -- I guess you would say they would have expertise in adding additive packages; for a specific application, I'm not sure. Like you could imagine, there would be material scientists at another organization that would purchase the material that would have knowledge of that. But again, it's going to depend on the specific circumstances.

Q. Despite the warnings in the MSDS not to use the Marlex resin in the human body, you're not aware of any studies that Boston Scientific Corporation conducted to determine whether or not using Marlex as a permanent implant in the tissues of women would be appropriate and safe; correct?

MS. STEELE: Object -- object to form.

A. Okay. Well, so, I mean, I might need you to repeat the question again. It was long, so it had a couple different parts.

Q. Despite the MSDS warning in the -- strike that.

Despite the MSDS warning not to use Marlex as -- in permanent implantable devices, are you aware of any clinical study that was done by

Boston Scientific to determine whether or not using the MSDS -- or using the Marlex resin would be safe and effective for women --

MS. STEELE: Object to form.

Q. -- before they placed it on the market?

MS. STEELE: Object to form.

A. Okay. So there's two -- I think, generally two different pieces there. So the first piece is this warning that you're referring to in the MSDS, which, you know -- I guess an MSDS from my understanding is something that's supposed to help the user who's going to be handling the raw material determine, you know, whether they're going to get hurt by this and how to actually properly treat it. Okay? So, you know, it would have something in there like could cause abrasion on your skin or an irritation or what to do if like some of the dust gets in your eyes or something like that. That's what you typically see with an MSDS.

What I typically do not see with MSDSs are end-use-type things. So what you typically don't see is recommendations as to what someone can or can't do with a material on an MSDS. It's just

not really the purpose of an MSDS.

Now, that said, in my experience I have seen that from time to time, and it's almost always in a circumstance where somebody is attempting to avoid any liability associated with it. So, you know, they don't have any testing as to determine whether or not it's safe. They're just saying if you use this, I -- we're not liable for doing it. And I have a number of circumstances that -- in materials in my lab where that -- literally, that's what's going on.

So that's with the MS- --

Q. Sorry. Go ahead.

A. So I'm saying, that's with the MSDS. So first of all, you know, could someone have a conversation based on that with the supplier, sure, related to the end use. But that in and of itself is not some kind of scientific proof that you shouldn't do that. It could very well be an indicator of liability.

Q. Are you -- are you aware that once the supplier of the Marlex found out that it was being used in permanent implantable medical devices by Boston Scientific, that they refused to supply the

Marlex resin to Boston Scientific?

MS. STEELE: Object to form and mischaracterizes the evidence.

Q. Are you aware of that?

A. Well, so if -- if that's the case, it wouldn't surprise me at all. Just because, you know, these people are selling resin. They're -- they're not incorporating in their business strategy ways to handle medical liability. That's not their business. So that wouldn't surprise me at all.

Q. Well, have you -- have you talked to anybody at Phillips?

A. No.

Q. Or Chevron?

A. No, it's just something based on my experience that I see with a handful of things.

Q. Have you asked Chevron or Phillips specifically why that language was included in their MSDS?

MS. STEELE: Object to form.

A. Well, I think I saw deposition testimony from somebody where they were saying that -- that there wasn't really any scientific tests done; it

was just something put in, and I think it was even discussed how their -- it was like in consultation with lawyers which, again, is exactly what I would expect.

Q. Did you ever determine why -- did you specifically ask or read any depositions concerning why Boston Scientific would have stopped or -- strike that.

-- why Chevron would stop producing or supplying Marlex after they determined or found out that the material was being used as permanent implant by Boston Scientific?

MS. STEELE: Object to the form. Mischaracterizes the evidence.

A. Did I specifically ask those questions? No. As I said, I just have the information that I had from just the deposition testimony and my own experience with MSDSs.

Q. Okay. So to the extent that Chevron or any supplier refused to continue to supply Marlex, you have no specific understanding based on deposition testimony or discussions with company representatives why that decision was made?

MS. STEELE: Object to form.

A. Well, no, I mean, what I said is I have some evidence as to why it wasn't made. So what I know is that there was no discussion of any scientific studies that were behind it. So I know that. And I -- like I said, I have my own personal understanding of MSDSs, and I've seen this before. So I don't know if anybody specifically and explicitly said why they did it; I just know that it wasn't because of scientific reasons and it was in consultation with their attorneys.

THE WITNESS: Are we at a point to take a lunch break, or --

MS. STEELE: Dan, how much more? It's --

MR. THORNBURG: I'm almost done. We can take a break if you want, but I'm almost done. I'm just going through -- I have a couple more questions.

MS. STEELE: Okay. So you think you'll be done by like 2:00, 2:15?

MR. THORNBURG: Yeah. Definitely.

MS. STEELE: Is that okay?

MR. THORNBURG: Well, maybe 2:30.

THE WITNESS: Why don't we take a break

and come back.

MS. STEELE: How long -- I think we need to take a break. I mean, he hasn't eaten.

MR. THORNBURG: Yeah, we -- that's fine. That's fine.

MS. KROTTINGER: 30 minutes?

MS. STEELE: What?

MR. KROTTINGER: 30 minutes?

MS. STEELE: 30 minutes is fine. We can run downstairs and get something.

THE WITNESS: Okay.

THE VIDEOGRAPHER: We're going off the record. The time is 1:52 p.m.

* * *

(Whereupon, a brief recess was taken.)

* * *

THE VIDEOGRAPHER: We're going back on record. The time is 2:35 p.m.

MR. THORNBURG: Let's go ahead and mark -- I think we're on Exhibit 7.

MS. KROTTINGER: Eight is the next one.

MR. THORNBURG: Exhibit 8, the amended materials considered list.

(SMITH Deposition Exhibit 8 was marked

for identification.)

Q. Is it marked and in front of you, Doctor?

A. Yes.

Q. Okay. Now, Doctor, I went through your materials list, and I didn't -- or I couldn't identify any specific publication that related to Upholds and the risks of Upholds for patients who are implanted with them. Is that -- is that a fair characterization?

MS. STEELE: Object to form.

A. I don't recall specifically doing an analysis of Uphold and the specifics risks for patients of like complications related to Uphold.

Q. Okay. And so you won't offer opinions at trial concerning Uphold and the specific risks as documented in the publication; is that correct?

A. With regard to the specific risks of complications in publications, no.

Q. You don't know what the range of dyspareunia is for Uphold?

A. No.

Q. Do you know what dyspareunia means?

A. No, I -- the name's not ringing a bell.

Q. Okay. Painful intercourse?

Have you heard that Uphold can cause painful life-altering complications in women?

MS. STEELE: Object to form.

A. Well, what I know is that there are complications that are discussed with patients, and there are complications that are recorded during visits. I did not do an analysis of that and I don't have opinions on it.

Q. You don't know what the risk of dyspareunia or painful intercourse is with regard to Uphold; correct?

A. Not off the top of my head, no. That would be something you'd have to talk to a doctor about.

Q. Do you know what the failure rate of the Uphold product is?

A. Not off the top of my head, no.

Q. You're not going to offer opinions at trial concerning the risk of dyspareunia or the rate of failure as it relates to Uphold; correct?

MS. STEELE: Object to form.

A. I'm not going to be specifically talking about rates, no.

Q. Do you know what the risk of extrusion means?

A. Extrusion, um, if you're referring to a complication from a patient that's called extrusion, no.

Q. Okay. So you're not going to offer any opinions at trial concerning the rate of extrusion in patients treated with Upholds?

A. No, not to my knowledge, no.

Q. You don't even know what extrusion means.

MS. STEELE: Object to form.

A. Well, I mean, I know what erosion means biologically; it sounds like it may be similar to that. But if there is a difference, then, no, I'm not aware of that.

Q. Do you know what the rate of erosion is for patients treated with the Uphold devise?

A. Not off the top of my head, no.

Q. You're not going to offer any opinions at trial concerning the rate of erosion concerning the Uphold device; correct?

A. No. Not to my knowledge.

Q. You don't know what the rate of the need to undergo additional operations to treat complications is with respect to the Uphold device; correct?

A. No.
Q. And you won't offer opinions at trial concerning the same; correct?
A. No.
Q. You don't know what the rate of de novo pelvic pain is in women treated with the Uphold product; correct?
A. No.
Q. You're not going to offer opinions at trial concerning the same; correct?
A. No.
Q. You don't know what the rate of de novo urinary dysfunction is with respect to women treated with the Uphold product; correct?
A. No.
Q. You won't, therefore, offer opinions concerning the same.
A. No.
Q. Were any of those risks relevant in any way or important in any way in understanding or rendering opinions concerning the biocompatibility of the Uphold device?
MS. STEELE: Object to form.
A. Well, what I would say is that you'd have to

talk to a doctor about it because I know there's different complication rates and complications that are discussed with patients, and every different situation very well could be different. So no, I did not feel like I needed to take that into account in the analysis for my report.

Q. And the same for the Obtryx, the Pinnacle, and the Solyx; you didn't go out and look at the epidemiological studies to determine what the rate of complications were with respect to those products either; right?

A. No.

Q. And you're not going to therefore offer any opinions concerning the same at trial; correct?

A. No.

Q. And the risk of complication to patients treated with the Uphold, the Pinnacle, the Solyx, the Obtryx, those weren't important for you to consider in rendering any of the opinions in this case; is that correct?

MS. STEELE: Object to form.

A. Not the opinions in my report, no.

Q. Now, I'm going to try to streamline this if I can because I know everybody wants to leave, and

I don't blame you.

But another article that you referenced in your expert report is the Clavé article; correct?

A. Yes.

Q. Okay. And generally speaking, the authors concluded that in a hundred patients that they evaluated explanted polypropylene mesh, that the polypropylene had undergone in vivo degradation; correct?

MS. STEELE: Object to form.

A. With the stipulation I'm pretty sure that they said that it could have been biological material.

Q. Well, their opinion was that polypropylene is not inert; right?

A. Well, that's in the title. I will just repeat again that they did say in this study that what they observed could have been biological material.

Q. If you -- let's go ahead and mark really quick Exhibit No. 9, the Clavé publication.

(SMITH Deposition Exhibit 9 was marked for identification.)

Q. Do you have Exhibit 9 in front of you, Doctor?

A. It's being passed to me.

MS. STEELE: He has it now.

Q. Do you have it now?

A. I do, yes.

Q. Okay. If we look at Exhibit 9, first page, under the Abstract section, do you see where it says "Conclusions"?

A. Yes.

Q. And this conclusion is that, "The study provides evidence contrary to published literature characterizing the polypropylene as inert in such applications."

Did I read that accurately?

A. Yes, you did.

Q. Okay. And the title of the publication is "polypropylene as a reinforcement in pelvic surgery is not inert"; correct?

A. Yes. That's what the title says.

Q. And the conclusion -- you agree with me, the ultimate conclusion of these researchers was that polypropylene undergoes in vivo degradation; correct?

MS. STEELE: Object to form.

A. Well, so, you know, we could -- just to say, we could be talking about two different things. So, you know, inert, depending on what you mean by that and who says it, it can have different meanings. Right? I mean, inert can have to do with its interactions with the body and even the ability for things to deposit on the material. So that's one definition of inert. And again, in terms of oxidation, it specifically says that you can't necessarily say this is oxidation because the signals may be of biological origin.

Q. Are you suggesting that these -- you read this publication; correct?

A. Yes.

Q. You understand that or understood when you read this publication that Dr. Clavé and the other co-authors concluded or used the word "inert" to mean that it's unstable in the human body over time, that it will degrade; correct?

MS. STEELE: Object to form.

A. Well, what I'm saying is that they're saying an inert -- if you think about the word "inert," it has to do with the body and the material itself. I

was just saying that some people use the word differently. So in this article, it could very well be that they determined that -- they are determining they think that this is degradation, but I will just say that they put in here that it could be because there was a material of biological origin. So they preface their conclusion by saying that that may be what's going on.

Q. They did a number of studies including -- in addition to FTIR; correct?

A. Yes. So they did other studies as well.

Q. So they did FTIR and they -- their FTIR spectrum -- one of the spectrums that they repeatedly saw was at 1730 reciprocal centimeters; right?

A. Yes.

Q. And they said that could correspond with the absorption of ester carbonyl groups which is likely from esterified fatty acids; right?

A. Right, so that's one source of a signal in that area where you could get something that's showing as positive.

Q. They also did scanning electron microscopy; right?

A. Yep, which is a visual analysis.

Q. A visual analysis that you've performed in the past to look at the integrity of the morphological features of products you've looked at; correct?

A. Right. In this case you're looking at what would be biological material in the product underneath of it, but yes.

Q. These experts or these researchers also did DSC?

A. Yes.

Q. And they concluded based on their FTIR and/or their scanning electron microscopy and the DSC that polypropylene is not inert --

MS. STEELE: Object.

Q. -- right?

A. Right, so they're concluding that; but as I've said before, if biological material's on the surface, that would be another interpretation of all of this data. And, in fact, they even mention that as a alternate explanation in the manuscript.

Q. Their conclusion, though, was that the polypropylene is not inert; correct?

A. That's their conclusion, yes.

Q. Would you disagree with their conclusion?

A. Yes. But I would agree with the alternate possibility that they mention as being viable as well.

Q. Can it be both, Doctor?

A. Well, whenever you're looking at it if there's biological material on it, that's what you would be able to see. Right? So, you know, even these SEMs that you're looking at, you know, you're looking at SEMs of fibers on the left and you could use a scale bar there to determine what the diameter of the fiber is, and then over on the right and you look at it and the fiber's bigger.

Q. Is it your opinion that it can't be both? It can't be degraded polypropylene and some biological material on the outer layer of the mesh; is that what your opinion is?

MS. STEELE: Object to form.

A. So as we discussed earlier, it's my opinion that you could have both; but when you look at this, if you're scanning the surface and biological material's on the surface, that's what you would detect.

Q. So I just want to summarize really quick.

You disagreed with the ultimate conclusions by Clavé et al. that polypropylene is not inert; you disagree with Dr. Wood who demonstrated and concluded according to her findings that polypropylene degrades in vivo; you disagree with the Mary article and the scientists, her co-authors, that found that polypropylene degrades in vivo; you disagree with Costello who concluded that polypropylene degrades in vivo; and you disagree with Dr. Liebert from 1976 who concluded that unstabilized polypropylene degrades in vivo; correct?

MS. STEELE: Object to form.

A. With the stipulation that in each of those cases their authors literally said there could be an alternate explanation for some of these signals, I disagree with the ultimate conclusion and agree with a whole different set of literature that comes to the conclusion that it's not oxidatively degrading.

Q. Well, we know that you agree with Dr. Thames; right?

MS. STEELE: Object to form.

A. Well, so what -- right, so what Dr. Thames

shows is that even after 11 and a half years, you can see that there's a pristine fiber underneath of the biological material.

Q. Okay. So we'll put Dr. Thames on the other side of all of the peer-reviewed publications, right, and we'll put you over there with Dr. Thames; is that fair?

MS. STEELE: Object to form.

Q. You agree with Dr. Thames; right?

A. What I'm going to disagree to is sides because I think all these articles provide the possibility of there being so -- there being biological material on there. So it's going to be very difficult to put even the ones you just discussed with me on a side.

Q. Well, you just testified that you disagreed with all of their ultimate conclusions that polypropylene will degrade in vivo.

A. Well, so, no, so they said that one ultimate conclusion was that there could be biological material that is responsible for some of the signals that they're seeing. So that's a conclusion of the paper. There's also --

Q. Their -- their ultimate conclusion was

polypropylene degrades in vivo. We can go back and look at all of the publications again. We can look at, you know, Dr. Liebert, who concluded that the unstabilized polypropylene degraded, of that you disagree with that and you have other findings that you point to that disagree with that; but his ultimate conclusion was unstabilized polypropylene will degrade. You disagree with that.

MS. STEELE: Object to form and characterization by counsel.

A. Yeah, I disagree with some of the things in the manuscript, but I agree with some of the other conclusions in the manuscript. These are not just all one-sided manuscripts.

Q. When we're talking specifically about in vivo degradation, to the extent that any of those authors or scientists concluded that polypropylene degrades in vivo, you would disagree with that conclusion?

MS. STEELE: Object to form.

A. Yeah, I mean, I guess I would disagree with your categorization of the manuscripts. I think what manuscripts are doing is showing all the data and discussing that data. They're saying there

could be alternate explanations. That's very common in scientific manuscripts. That's not --

Q. Let me ask the converse of that. To the extent that all these authors that we've already talked about found that polypropylene does not degrade in vivo, you'd agree with that?

MS. STEELE: Object to form.

A. Well, so based on my reading of the literature, if someone had a manuscript and they went through it and suggested that the polypropylene doesn't degrade, that would be consistent with the vast majority of evidence that I've seen.

Q. To the extent that these authors Clavé, Costello one and two, Celine Mary, Clavé, Liebert have concluded that polypropylene does indeed degrade -- undergo degradation inside the body, you would disagree with that; correct?

MS. STEELE: Object to form.

A. Yes, I would disagree with the conclusions, and there's specific reasons because the biological material would explain all of these things.

Q. Okay. And you would agree with all the findings in Dr. Thames' report; correct?

MS. STEELE: Object to form.

A. Well, I guess I didn't go through and analyze if there was anything in there in the methods that I disagree with. I can tell you that with regard to degradation of the polypropylene, it was a thorough study that showed the results of multiple steps of cleaning and in between those steps did analyses of the material, and it seems very clear in that study that it's not degrading.

Q. Now, Dr. Thames, his publication doesn't relate to Marlex polypropylene; right?

MS. STEEL: Object to form.

A. I'm not so sure I'd say that, I mean, basically, you know, my understanding of this is that even other experts for plaintiffs like Dr. Mayes is saying that polypropylene's polypropylene, so.

Q. Are you saying polypropylene is polypropylene?

A. Well, I'm saying that if you have this stabilized polypropylene mesh that's in the body for 11 years and you can crack films that look exactly like the films that everybody else is saying is oxidized polypropylene and underneath of

it is a pristine fiber that has the manufacturer's striations, it's pretty clear to me that that would apply to both.

Q. My question was pretty easy. So are you saying that polypropylene is polypropylene is polypropylene; is that your opinion?

MS. STEELE: Object to form.

A. I'd say that with regard to my analysis of the literature here in my report, I think the answer is yes. In all regards, details of concentrations of things, maybe not. I haven't done that analysis.

Q. Have you read the deposition of Dr. Barbol who testified on behalf of Ethicon? He was a scientist at Ethicon and conducted and looked at the degradation studies that Ethicon did internally. Have you read that?

A. I don't believe so, no.

MS. STEELE: Objection to evidence not in this case.

Q. If Doctor -- strike that.

MR. THORNBURG: What's that?

MS. STEELE: I don't think we would be allowed to show them to him, but --

MR. THORNBURG: It's in the same court.

MS. STEELE: Okay.

MR. THORNBURG: It's public information.

Q. If Dr. Barbol has testified that Ethicon's Prolene undergoes in vivo surface degradation, that the polypropylene actually degrades, would you also disagree with Dr. Barbol?

MS. STEELE: Object to form.

A. I haven't seen the evidence that he uses to make that conclusion, so.

Q. Did you know that Ethicon performed numerous, dozens upon dozens of internal studies looking specifically at whether or not Prolene polypropylene will degrade?

MS. STEELE: Object to form.

A. I'm not aware of Ethicon studies.

Q. How many Boston Scientific studies were done internally by Boston Scientific to determine whether or not if Marlex polypropylene mesh would undergo in vivo degradation?

MS. STEELE: Object to form.

A. Well, I don't know if I've seen all the documents associated with Boston Scientific, and I -- even if I did, I don't know if I'd remember.

So I think my answer is I don't remember.

Q. So have you seen a single document by Boston Scientific that tried to answer the question internally whether or not Marlex polypropylene materials that they were using in their pelvic mesh devices would degrade?

MS. STEELE: Object to form.

A. And I know they went through the studies to show FDA clearance which --

Q. That wasn't my question. That wasn't my question. My question was, did Boston Scientific provide to you any internal study demonstrating that Boston Scientific actually did internal corporate studies to determine whether or not its Marlex polypropylene would undergo in vivo degradation?

MS. STEELE: Object to form.

A. Okay. So internal studies, I don't remember.

Q. Did you ask them if they had any internal studies?

A. No, I didn't ask.

Q. Doctor, what publications in your amended reliance materials list support your opinion that

Marlex polypropylene will not degrade in vivo?

MS. STEELE: Object to form.

A. Well, I'd say first of all, the ones that I cite in my report. Then I go through the specific details of why I rely on those.

Q. Are there any additional studies outside of your expert report in your materials reliance list that you claim support your opinion that Marlex does not degrade in vivo?

MS. STEELE: Object to form.

A. I mean, I read all of these things and I would say in all of them that you have in front of you there was nothing there that made me believe that it did degrade. So as a whole, this materials considered list suggests to me that polypropylene is not degrading.

Q. Have you ever looked at Dr. Thames' expert report?

A. Dr. Thames' expert report, I'm not sure I remember.

Q. Did you ever talk to Dr. Thames?

A. No.

Q. Ever met with Dr. Thames?

A. Since this trial started, no. Or since --

sorry, not the trial, my apologies. Since I was retained for this case, no.

Q. Have you spoken with Dr. Thames before?

A. I may have seen him before, spoke. I'm not good friends with him.

Q. You have listed on your reliance list Dr. Ostergard's publication or publications by Dr. Ostergard; correct?

A. Yes.

Q. And Dr. Ostergard as you know from reading his publications has concluded that polypropylene will undergo in vivo degradation; correct?

A. I don't have a copy of that article. To refresh my memory, I don't recall specifically what that article talks about off the top of my head.

Q. What about Dr. Iakovlev; did you review Dr. Iakovlev's publication?

A. Sorry, could you spell the name.

Q. Iakovlev, I-A-K-O-V-L-E-V.

A. I've seen those publications, yes.

Q. And you know from reviewing his publications that he's concluded that polypropylene undergoes in vivo degradation; correct?

A. I believe he concludes that, yes.

Q. And you would disagree with Dr. Iakovlev; correct?

A. I do.

Q. And to the extent that Dr. Ostergard opines that polypropylene undergoes in vivo degradation, you would disagree with Dr. Ostergard?

A. Yeah, I mean, I don't remember that article off the top of my head. I'd have to look at it but...

Q. To the extent that he did, you'd disagree; right?

MS. STEELE: Object to form.

A. You know, I'd say, again, I'd like to look at or remember the details of why an individual would say that. But I think that from my review of the literature, it's my opinion that it's not degrading in vivo.

Q. Let's go ahead and mark as Exhibit No., I think 10, the Ostergard degradation paper entitled "Degradation, infection and heat effects on polypropylene mesh for pelvic implantation: what" we -- "what was known and when it was known."

(SMITH deposition Exhibit 10 was marked for identification.)

Q. Have you looked at this Dr. Ostergard article?

A. I do remember this article now, yes.

Q. And you recall that Dr. Ostergard in this paper goes through a time line of when it was known that polypropylene will undergo in vivo degradation?

MS. STEELE: Object to form.

A. Well, the time line here has a bunch of different pieces of information that I believe Dr. Ostergard would say that, you know, someone could look at all of this and draw a conclusion. There is some discussion here at the very end about many publications and detailing things like degradation mechanisms and heat exposure. But this is not a detailed study; it's just referencing a bunch of other things.

Q. But you understand and you understood when you read this paper that Dr. Ostergard is stating in this paper that it's been known and it was known before mesh manufacturers began to sell polypropylene mesh material that polypropylene mesh would degrade in vivo; correct?

A. Well, I -- I -- I'm trying to look for that

ultimate conclusion here. He's citing certain papers, some of which I think we probably discussed, and he's citing other things like bacteria adherence, and it's just a compilation of a bunch of different things here.

Q. If you look at the first page, beginning where, "There has been a lack of dissemination"; do you see that?

A. Yes.

Q. "There has been a lack of dissemination of information regarding many of the characteristics of polypropylene mesh especially the many factors which are implicated in the complications that our patients experience postoperatively."

Did I read that correctly?

A. I think you did read that correctly, yes.

Q. And then he talks about some of the meshes of when they were cleared by the FDA; correct?

A. Yes.

Q. And then he goes on to say, "I will concentrate here on those factors known to influence the behavior of mesh in vivo until 2003, when many more new meshes were cleared by the FDA. Heat effects and degradation will be summarized.

Relevant information has accumulated since the 1950s and was available in the medical literature for many years before FDA clearance of various meshes and mesh kits as outline below."

And then he goes through and talks about when it was known that bacteria will adhere to mesh fibers and could lead to infection; correct?

A. Yes.

MS. STEELE: Object to form.

A. Yes.

Q. And then he goes through and says -- and outlines when it was known, based on his research, when degradation was known to occur in vivo with polypropylene mesh devices, and he outlines that for us; correct?

A. Well, he cites a paper that makes a conclusion. That particular paper said based on the evidence they have, that there's degradation. He's not concluding there's degradation; he's citing other people.

Q. Have you read any other of Dr. Ostergard's publications where he concludes that polypropylene degrades in vivo?

MS. STEELE: Object to form.

A. I don't remember.

Q. If Dr. Ostergard ultimately concluded in any of his publications that polypropylene mesh used in the treatment of pelvic organ prolapse and stress urinary incontinence undergoes in vivo oxidative degradation or some other form of in vivo degradation, would you agree or disagree with Dr. Ostergard?

A. Well, I mean --

MS. STEELE: Object to form.

A. -- I guess I'd love to see the information that he's using, the tests that were done. But like I said, my review of the literature suggests that there's no degradation of the polypropylene and, in fact, that the conclusions that are made by those who say that there is degradation, most notably the way the fibers look is the most common thing that people use, and my research suggests that that is a layer of biological material.

Q. Now, you've also reviewed Dr. Jongebloed?

A. The name sounds familiar, yes.

Q. He's got a publication dating as far back as the 1980s; correct?

A. Are these the studies in the eye?
Q. Right.
He's got a number of studies. He's got eye studies and non-eye studies.
A. Okay.
Q. Subcutaneous. Have you looked at Jongebloed's subcutaneous studies?
A. I can't recall if I've seen the subcutaneous studies. I do recall seeing the eye study.
Q. Okay. And in -- with respect to the eye study at least you understand that Dr. Jongebloed opined or concluded in his publications that polypropylene mesh will degrade?
A. Yeah.
MS. STEELE: Object to form.
A. From my recollection it's based on visual observation of a coating on the outside of the fibers.
Q. And I want to clarify because I think I made a mistake. His conclusion was that polypropylene sutures will undergo in vivo degradation; correct?
MS. STEELE: Object to form.
A. Right. Same answer that I just gave for sutures, yes.

Q. And you disagree with Dr. Jongebloed's opinion that polypropylene sutures will undergo in vivo degradation; correct?

MS. STEELE: Object to form.

A. Yeah, I think that the primary reasons for people concluding that can be explained by a coating of biological material.

Q. You disagree with Dr. Jongebloed's opinion that it actually is degraded polypropylene and not some sort of biological material that's breaking on the outer layer of the polypropylene fibers; correct?

MS. STEELE: Object to form.

A. Yes, based on what I've seen, I think that what is seen, for instance, in that study, is a layer of biological material instead of degradation.

Q. And Dr. Iakovlev, I think you've testified that you disagree with his conclusions that polypropylene degrades in vivo; correct?

A. Yes.

Q. Other than Dr. Thames and Dr. de Tayrac, what other publications do you rely on where the conclusion from the researchers or the authors of

the publication was that polypropylene does not undergo in vivo degradation?

MS. STEELE: Object to form.

A. Yeah, I mean, so, again, we're doing this dichotomy of things. I think that there's plenty of conclusions and speculation in all of these papers that we were talking about that it could be a layer of biological material, so I would not limit it to those two papers.

But I do think that, of note, those two papers come up with and focus on cleaning mechanisms. So the cleaning mechanic --

Q. I'm not --

MS. STEELE: He's still answering.

Q. I'm sorry, I thought you were done. Were you done?

A. No.

MS. STEELE: Continue.

A. So I was just saying that those two particular papers focus on cleaning mechanisms, and especially the Thames article more recently focuses on a multistep cleaning mechanism where you can literally see like the various results from the various steps of the cleaning. So in that regard,

it's very clear in those manuscripts what's going on. But in the history of these papers, many of which we've discussed, there's plenty of evidence that this is a coating of biological material.

Q. Provide me with one specific publication other than Thames or Dr. de Tayrac where the conclusion was that polypropylene sutures or mesh do not undergo in vivo degradation.

MS. STEELE: Object to form.

Q. Just one. This is your opportunity.

A. Yeah, so I already -- I already gave you a number of them. And there's conclusions in there that say that it could be that and that could be an alternate explanation. Whether or not it's the final ultimate conclusion or not, which is what you're trying to force me into, is a different story.

But I think what I would point you to is all the studies that do not show it. So what you wouldn't have happen is somebody publish a paper that says we didn't find any oxidative degradation because everybody would suggest and note that there's not going to be oxidative degradation because it's not a degradable material. So it's

not going to be a super-publishable thing.

Q. You're saying there aren't publications that you can point to that -- where the ultimate conclusion was that polypropylene doesn't undergo in vivo degradation because when those studies were done they decided not to publish it because everybody knew that polypropylene wouldn't undergo in vivo degradation; is that your testimony?

MS. STEELE: Object to form.

A. What I'm saying is to, in addition to all that I just said, there's going to be the possibility of situations where somebody looked at a polypropylene implant, saw no harmful effects whatsoever, and wouldn't have necessarily published that nor would it have been something an editor would have been excited to accept because of all of the history of safe use of polypropylene. So all I'm saying is, is that it's a more --

Q. Other than speculation, Doctor, what is the basis for that statement that you just made?

A. Because --

MS. STEELE: Object to form.

A. -- because showing that polypropylene degrades would be a provocative thing. It's

something that goes against many years of established use. You don't see widespread failures, so you would expect that the material would continue to be stable. So to show that there's some degradation is kind of a provocative thing; it's something that editors would be more likely to entertain for a publication. So what I'm saying is I based my conclusions off the literature that's in my report. That's what they're based off of.

Q. Can you give me the name of any -- any scientist anywhere in the world who you've spoken to who you've been in contact with who has told you that they decided not to publish their findings on in vivo implantation of polypropylene because it wasn't provocative because it didn't show degradation? Tell me one scientist that you know of who's ever done that.

MS. STEELE: Object to form.

A. That's not what I'm saying. I have not talked to scientists who have told me that and that wasn't my point.

Q. Okay. So other than speculation, you've got no other foundation to state that that has been

what's happened?

MS. STEELE: Object to form.

A. I would just cite the very long history of safe use.

Q. Doctor, you've never even looked at the epidemiological studies that looked at the dangers or the risks or the complications associated with the Uphold, the Obtryx, the Solyx, or any of Boston Scientific's products.

MS. STEELE: Object to form.

Q. You never even looked at that epidemiological data.

MS. STEELE: Object to form.

Q. Right?

A. I have not looked at that epidemiological data.

Q. Is Uphold on the market anymore, Doctor?

A. Um, my understanding is that Uphold is not currently on the market.

Q. Is the Pinnacle on the market anymore, Doctor?

A. I don't recall. In fact, maybe it's one that I thought I heard is not on the market and the other one is. I don't remember, I'm sorry.

Q. You don't know -- you don't even know which products are on the market currently, do you?

MS. STEELE: Object to form.

A. Um, I don't, but I don't understand how that's relevant to my opinions.

Q. Well, you keep on saying decades of safe use, but you haven't even looked at the epidemiological studies concerning Boston Scientific's pelvic mesh devices. You don't know which products are on the market or aren't on the market anymore. Do you know why Boston Scientific stopped marketing some of their pelvic organ prolapse devices?

MS. STEELE: Object to form. Calls for speculation. Argumentative.

A. It was like three or four questions there. I remember the last one.

Q. Okay.

A. Which is I don't know why specifically Boston Scientific would have chosen to market or not market something.

Q. Have you read the FDA 522 orders?

A. I don't recall reading FDA 522s.

Q. Did you know that the FDA, just before

Boston Scientific decided not to -- to no longer sell some of their pelvic organ prolapse devices, that the FDA had conducted an analysis and had determined that Boston Scientific had not demonstrated safety and that the studies that were currently available did not demonstrate safety and had required Boston Scientific to undertake post-market clinical trials to determine the safety and efficacy of their Marlex mesh pelvic organ prolapse product devices? Are you aware of any of that history?

MS. STEELE: Object to form; mischaracterizes the evidence.

A. Yeah, so you might have to repeat that question. It was very long.

Q. Were you aware of the history concerning the FDA's 522 orders of post-market clinical trials that needed to be done in order for Boston Scientific to continue to market some of their pelvic organ prolapse Marlex mesh devices?

MS. STEELE: Object to form.

A. As I said before, I have not read the 522s.

Q. Okay. Are you aware of the re-classification that's been done by the FDA?

MS. STEELE: Object to form.

A. I'm not an FDA expert here, so I'm not aware of the specifics of it, no.

Q. Is it fair to say that you haven't looked at all the epidemiological data to determine on your own the safety of the Uphold, the Pinnacle, the Obtryx, the Solyx devices?

MS. STEELE: Object to form.

A. No, that's outside of the scope of the opinions that I put in my report.

Q. You're not going to offer regulatory opinions at trial; correct?

A. No.

Q. You're not going to suggest to the ladies and gentlemen of the jury that Uphold is a safe product; correct?

MS. STEELE: Object to form.

A. No, I mean, my opinions are contained in my report. There's a lot of things associated with a product. Doctors, you'd have to talk to them about this as well. I'm not providing testimony on all of those things.

Q. So to answer my question so the record's clear, you're not going to offer opinions at trial

that the Uphold product is safe as a permanent implant for the treatment of pelvic organ prolapse in patients?

MS. STEELE: Object to form; asked and answered.

A. No, I'm only providing the opinions that are in my report.

Q. Okay. You're not going to offer the opinion at trial that the Pinnacle is a safe and effective treatment option for women; correct?

MS. STEELE: Object to form.

A. Like I said, I'm not sure how to answer this. I think I already answered it. My opinions that I'm going to testify on are in my report. So I'm not going to be going into clinical safety, efficacy; that's not my area of expertise.

Q. Right. Without having reviewed all of the material concerning the safety and efficacy of the product, you can't offer an opinion that a product is safe and effective; right?

MS. STEELE: Object to form.

A. Correct.

Q. You're not going to offer any opinions at trial that, for the same reason, that the Obtryx

device is a safe and effective product for the treatment of stress urinary incontinence because you simply haven't looked at all of the epidemiological studies concerning that product; correct?

MS. STEELE: Object to form.

A. Correct.

Q. And the same with the Solyx; correct?

MS. STEELE: Form.

A. I'm not going to be offering opinions on clinical safety and efficacy and epidemiological studies on these materials, no.

Q. You're not going to offer any opinion that any one of the plaintiffs in any of the cases that you've been disclosed as an expert wasn't harmed as a result of being implanted with either the Uphold, the Pinnacle, the Solyx, or the Obtryx; correct?

MS. STEELE: Object to form.

A. No.

Q. Because that would be a medical opinion and outside of your expertise; correct?

MS. STEELE: Form.

A. Yes.

Q. You're not going to offer the opinion at

trial that the Uphold, the Pinnacle, the Solyx, or the Obtryx were not defectively designed --

MS. STEELE: Object to form.

Q. -- correct?

A. What I would say is just to the extent that my report's opinions talk about the polypropylene itself as not --

Q. You're going to limit your opinions -- you're going to limit your opinions to, essentially, to degradation; is that fair?

MS. STEELE: Object to form.

A. Degradation and the local response, yes.

Q. Having not looked at the design history file, you can't offer an opinion about whether or not the company has performed something below the standard and has marketed a product that was in some ways defective and harmful to patients; correct?

MS. STEELE: Object to form.

A. Besides what we've talked about, I'm not offering opinions on that, no.

Q. And you haven't reviewed FMEA? Do you know what FMEAs are?

A. I think it's basically a failure modes

analysis. I'm not offering opinions -- I'm not offering opinions on that.

Q. And you won't be offering any opinions concerning the adequacy or inadequacy of any of the labeling that was provided to physicians or to patients; correct?

A. Correct.

MR. THORNBURG: Now, let me just go off the record for one moment.

THE VIDEOGRAPHER: Going off the record. The time is 3:26 p.m.

(Whereupon, a recess was taken.)

THE VIDEOGRAPHER: Beginning of disk four, going back on the record. The time is 3:32 p.m.

MS. STEELE: Dan, do you want to pass witness to Katy?

MR. THORNBURG: Yes. I'm passing the witness to Katy.

EXAMINATION

BY MS. KROTTINGER:

Q. Dr. Little, is this your first deposition in this litigation?

A. Yes.

Q. And how did you become a witness in this litigation?

A. Well, I mean, I guess -- I don't know the details of the legalese of this. I submitted a report. Exactly how I'm chosen to come give verbal testimony, I don't know.

Q. So Boston Scientific's counsel sought you out to be an expert in this litigation?

A. Yes.

Q. And your report dated October 24th of 2016, that's your first expert report that you drafted in this litigation?

A. That sounds -- that sounds right.

Q. And you've only written one report thus far?

A. I've only -- that I know of, I've only written one report.

Q. Have you read the expert reports of Dr. Spiegelberg or Dr. Badylak?

A. I don't believe I have, no.

Q. Do you know who Dr. Spiegelberg is?

A. I know who Dr. Spiegelberg is. I've never spoke to him. We haven't met.

Q. How about Dr. Badylak?

A. Yes, I know Dr. Badylak.

Q. Have you reviewed any of his work or studies?

A. Well, I mean, I guess he's been at the University of Pittsburgh since I came in 2006, so I knew him and generally aware of his work.

Q. Do you know him personally?

A. I do.

Q. Did you become involved in this litigation because of your relationship with Dr. Badylak?

A. No.

Q. Do you believe that polypropylene oxidizes inside the body?

A. Do I believe that it oxidizes inside the body? No.

Q. Zero percent, no oxidation whatsoever --

A. Hmm.

Q. -- that's your opinion?

MS. STEELE: Object to form.

A. Well, I think that the studies are very clear that it's not degrading. You know, zero percent, I -- I mean, is it possible that you have like a polymer chain on the surface that -- that can oxidize? I don't know. I mean, it depends on the details of the antioxidant package and how long

it's been in there. But I mean, geez, even after 11 and a half years, you can still see it's not degraded.

So I think if there is any surface level of oxidation which again we're talking about extremely thin layer on the surface, if anything, I can't say with a hundred percent certainty whether there's like a bond or two bonds or a hundred bonds, but I can tell you for sure that those numbers I just gave and even much bigger numbers than I just gave would make no impact on the material property of the system.

Q. But it's your opinion that polypropylene can oxidize inside the human body?

A. I think it can oxidize under thermal conditions. I think it's unclear; I've never seen anybody show that it can oxidize in the body. So I think no one knows.

Q. Are peroxides oxidative agents?

A. Peroxides are considered reactive oxygen species.

Q. And not to belabor this point because I think Dan went over this quite a bit, but do you believe that polypropylene is one hundred percent

inert?

MS. STEELE: Object to form.

A. I mean, if by inert you mean that it -- the most useful term for inert is that it maintains its ability to do its job over the period of time that it's intended to do its job, then I believe it is inert, yes.

Q. So if it -- so is that your definition of inert, an inert material?

A. Generally, that's the definition of inert that I think is useful. So, for instance, a definition of inert where, you know, there's any bonds that degrade or something, is a useless definition. Because, I mean, everything in the universe can -- there would be nothing that would be inert if that's the definition.

Q. Okay. Do you know what the foreign body response is?

A. Yes.

Q. Do you believe that the foreign body response to implanted materials is chronic?

A. Um, is it chronic? I think from what I've seen, I don't see evidence of a chronic inflammatory response. I will say that the foreign

body response is not necessarily a bad thing and actually required for healing. So just the fact that you have inflammation is not necessarily bad at all.

Q. Does the foreign body response ever stop?

MS. STEELE: Object to form.

A. Um, I think that we're going back to the same thing before, I guess it depends on your definition. Is it a useful definition or not. I mean, is there -- is there a -- is there a lymphocyte or a monocyte or something that goes in and that -- does that mean the foreign body response never stops? That would be sort of, I think, in my opinion, a useless definition. I don't think that there's evidence of a chronic inflammatory response which is what I think ultimately is going to -- if you have complications, then you can associate it with that. I don't see evidence of that. So I guess my answer is, again, that you have to be careful with what you are defining in order for it to be a meaningful question.

Q. Do you think different types -- different parts of the body have different reactions to

foreign bodies?

A. I think it's possible for you to have a different response to an implanted material in one part of the body than another one, yes.

Q. And earlier you testified that you're not an expert in the pelvic floor anatomy; correct?

A. I'm not an expert in the anatomy of the pelvic floor; correct.

Q. Do you think that the vagina acts differently to implanted materials than other parts of the body?

A. It may react differently.

Q. Do you know if it does or not?

A. Um, I mean, I guess I would say that I haven't extensively looked into what those differences would be, but I think that it's reasonable to believe that it's possible.

Q. Do you know whether or not there are peroxides in the vagina?

A. I think that there probably are. I mean, there's peroxides that are available as a result of a foreign body response throughout the body. So I don't think there's any reason to exclude that particular anatomy from that. Yeah, I mean, I'd

say the concentrations most people -- most people realize, I mean, the concentrations you're talking about are extraordinarily small.

Q. Okay. Turn to page 6 of your report, please. Okay. The first full paragraph, you state that, "The deposited collagen, both within the pores and around the mesh may contract. This is, again, an anticipated part of the foreign body response. Importantly, there is not the -- this is not the mesh itself contracting or 'shrinking' and certainly is not the polymer chains (that make up that material) shrinking."

Did I read that correctly?

A. Yes.

Q. Why did you include that opinion in your report?

MS. STEELE: Object to form; to the extent it calls for any attorney/client privilege and the protection of draft reports.

A. Well, what I was trying to say here is that most of the focus that I've seen in this question related to the polypropylene has to do with some supposed breakdown in the polymer structure leading to physical changes. What I wanted to point out

here is that there's a normal, necessary part of healing that goes on, and in that case there is the possibility of some contraction of that tissue. And by that I'm talking about on like the cellular and tissue level. What I wanted to make sure in the context of this and again, you know, the next section is on polypropylene is non-degradable, I wanted to make sure that any of this contraction that's a part of the expected foreign body response is not attributed to some kind of material change in the polypropylene that's causing the polypropylene to contract.

Q. So I just want to see if I understand this correctly. Your opinion is that if there is contracture, it's because the mesh -- or I mean the tissue is making the mesh contract through the healing process; is that accurate?

MS. STEELE: Object to form.

A. Yes. So the polymer itself is not going to contract. The tissue can.

Q. And the whole purpose of these mesh products is for tissue ingrowth; correct?

MS. STEELE: Object to form.

A. The whole purpose of this process is to form

this synthetic and biological -- I mean, it's not a true composite, but it's kind of like both of them together.

Q. So does this process cause the surface area of the mesh to decrease?

MS. STEELE: Object to form.

A. Hmm. Well, I mean, I guess it depends on what do you mean by surface area and how you're calculating it. If you fill it with biological tissue and now all that biological tissue is there and you're looking at just the surface area of this thing rather than what it was before which was this with pores, then the surface area would decrease.

Q. Do you know by how much?

A. No.

Q. Do you think it's important to know how much?

A. Um, do I think it's important to know? For what reason?

Q. I'm asking questions, not you.

So do you think it's important to know?

MS. STEELE: Object to form.

A. You know, could I imagine a question where

the surface area may be relevant to some output parameter? It's possible. But until I know what I'm understanding in regard to the surface area, I can't answer the question.

Q. Do you think it would be important for doctors to know whether or not the surface area of the product changed once it was implanted inside the human body?

MS. STEELE: Object to form.

A. I don't know, I mean, you'd have to ask a doctor.

Q. Do you know if Boston Scientific has done any research as far as this is concerned?

MS. STEELE: Object to form.

A. I don't know.

Q. Do you think they should have?

MS. STEELE: Object to form.

A. Um, I don't know. I think that's outside of the scope of my opinions in my report.

Q. Well, I mean, you have an opinion about whether or not the mesh contracts and shrinks once it's implanted inside the human body; correct?

A. I do.

Q. So you don't think that it's important for

Boston Scientific to have done some research in this regard?

MS. STEELE: Object to form.

A. Um, well, I mean, I guess the question I was trying to answer had to do with like surface area and, again, I maybe don't understand what specifically we're looking at in regard to the surface area changing. Could I imagine that it's important for Boston Scientific to have done studies related to this particular topic? I mean, I don't know. It's not my area of expertise. You'd have to talk to a doctor.

Q. If there was a 30 percent decrease in surface area of the mesh, do you think that that would tend to prove that the material is not inert?

MS. STEELE: Object to form.

A. Hmm, I don't know. I don't have the context to understand the 30 percent. And, I mean, I know these are put in tension-free. I know that they're put in a way where it's --

Q. The Uphold is not put in tension-free.

A. Oh okay.

MS. STEELE: Object to form.

A. I mean, it's -- this seems to be outside of

the area of my opinions, so I don't know if I have an opinion on this.

Q. So you can't say whether or not a 30 percent decrease in the surface area of the Uphold, for instance, would mean that it's not functioning as intended?

MS. STEELE: Object to form.

A. What I would say -- what I would say is this, and that's that tissue growth into this mesh is part of how it's supposed to work. The degree at which that tissue infiltrates and imparts its properties on the system and the degree at which the final orientation of the system is in order to impart its effect in the local biological environment, I don't know. That's not my area of expertise, so I can't answer the question.

Q. What if it decreased by 70 percent; would that mean that the mesh was not functioning as intended?

MS. STEELE: Object to form.

A. Well, I think what I'd want to know is some information -- again, this is not my area of expertise because it seems like it's -- what it's intended to do in terms of the tissue environment

and the support, a doctor would know that. So if somebody said that it was intended to shrink one percent and then you said that it shrinks 70 percent and the tolerance level for that was less than the difference between 1 and 70 percent, then you'd say it's not functioning as it was intended. But I don't know the details as to what percent was intended in the first place.

Q. So are you going to offer any opinions at trial of what rate of shrinkage is acceptable and is not acceptable?

MS. STEELE: Object to form.

A. No.

MS. KROTTINGER: Okay. No further questions.

MS. STEELE: Okay. I don't have any questions. Can we go off the record? Dan, are you--

MR. THORNBURG: I'm here.

MS. STEELE: I think we are all done.

MR. THORNBURG: Thanks, everybody.

THE VIDEOGRAPHER: That concludes the deposition. Going off the record. The time is 3:40 -- I'm sorry, 3:48 p.m.

(Signature waived.) CONCLUDED -- 3:48 P.M.

CERTIFICATE

COMMONWEALTH OF PENNSYLVANIA)
) SS.
COUNTY OF WESTMORELAND)

I, Dutcheen O. Cameron, a Registered Merit Reporter-Certified Realtime Reporter and Notary Public in and for the Commonwealth of Pennsylvania, do hereby certify that the witness, STEVEN LITTLE, Ph.D., was by me first duly sworn to tell the truth, the whole truth, and nothing but the truth, and that the above deposition was recorded in stenotype by me and reduced to typewriting under my direction.

I further certify that the said deposition constitutes a true record of the testimony given by said witness; that the foregoing deposition was taken at the time and place stated herein.

I further certify that the inspection, reading and signing of said deposition were waived by counsel for the respective parties and by the witness.

I further certify that I am not a relative, employee or attorney or counsel of any of the parties, or a relative or employee of such attorney or counsel or financially interested directly or indirectly in this action.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my seal of office this 19th day of February, 2017

Dutcheen O. Cameron, RMR, CRR
Notary Public